B3 User’s Manual

33718 MONITOR GIMA SPA B3

Patient Monitor

Rev. 2.0

GIMA

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1.1 CE Standard Information

Electromechanical safety standards met:

- EN 60601-1: 1990 + A1:1993 + A2: 1995 Medical Electrical Equipment, Part 1, General Requirements for Safety.
- IEC/EN 60601-1-2 :2001 Electromagnetic compatibility -Requirements and tests.
- EN 1060-1:1995 Non-invasive sphygmomanometers - Part 1: General requirements
- EN 1060-3:1997 Non-invasive sphygmomanometers - Part 3: Supplementary requirements for electro-mechanical blood pressure measuring systems
- EN ISO 9919:2005 Medical electrical equipment - Particular requirements for the basic safety and essential performance
of pulse oximeter equipment for medical use (ISO 9919:2005)
- EN 60601-2-27:2006 Medical electrical equipment - Part 2-27: Particular requirements for the safety, including essential performance,
of electrocardiographic monitoring equipment
- EN 60601-2-30:2000 Medical electrical equipment - Part 2-30: Particular requirements for the safety, including essential performance,
of automatic cycling non-invasive blood pressure monitoring equipment
- EN 12470-4:2000 Clinical thermometers - Part 4: Performance of electrical thermometers for continuous measurement
- EN 60601-2-49:2001 Medical electrical equipment - Part 2-49: Particular requirements for the safety of multifunction patient monitoring equipment

1.2 Read before Use

The followings are address and phone number for contacting information, services, and product supplies.

How to Contact Us

Purchase Inquiry	**GIMA SPA** VIA MARCONI, 1 – 20060 GESSATE (MI) ITALY Tel : ++39 02 953854209 Fax : ++39 02 95380056 E-mail : gima@gimaitaly.com
Manufacturer	**Bionet Co.,Ltd.** #11F, E&C DREAM TOWER III, 197-33, GURO-DONG, GURO-GU, SEOUL, SOUTH KOREA (ZIP 152-050) Overseas sales dept. Tel : +82-2-6300-6418
Service call	VIA MARCONI, 1 – 20060 GESSATE (MI) ITALY Tel : ++39 02 953854209 Fax : ++39 02 95380056 E-mail : export@gimaitaly.com
Technical support	For any technical questions or problems on the equipment, call; VIA MARCONI, 1 – 20060 GESSATE (MI) ITALY Tel : ++39 02 953854209 Fax : ++39 02 95380056 E-mail : export@gimaitaly.com
Web site	URL : http://www.gimaitaly.com URL : http://www.bio2net.com

In the event of malfunction or failure, contact us along with the model name, serial number, and product name of the equipment.

If you need the supply circuit diagram, component list, description and calibration instruction etc. you can contact us we will provide you with it.

Warranty Period

- This product is manufactured and passed through strict quality control and through inspection.

- Compensation standard concerning repair, replacement, refund of the product complies with "Consumer's protection law" noticed by Economic Planning Dept.

- We provide a 2-year warranty period for main body, but Accessory provides a 6 months warranty period.

- Warranty repair or replacement will be made by GIMA SPA Service Center at no charge for warranty period if properly used under normal condition in accordance with the instructions for use.

- Manufacturer or sales agency takes no responsibility for any kind of damage or breakdown that is caused by misuse and failure to maintain the equipment.

Warning, Caution, Note

For special emphasis on agreement, terms are defined as listed below in user's manual. Users should operate the equipment according to all the warnings and cautions.

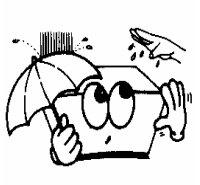
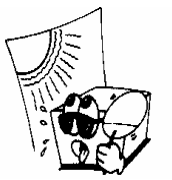
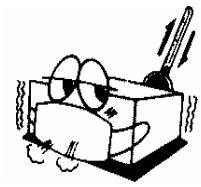
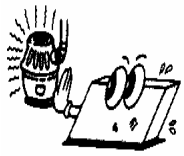
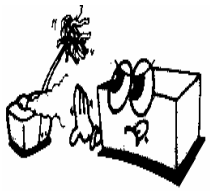
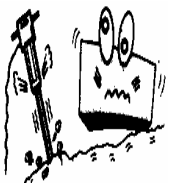
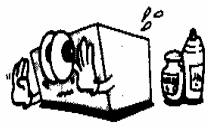
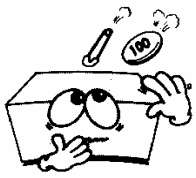
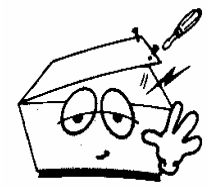
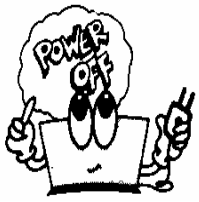
Warning
To inform that it may cause serious injury or death to the patient, property damage, material losses against the "warning" sign

Caution
To inform that it may cause no harm in life but lead to injury against the "caution" sign

Note
To inform that it is not dangerous but important "note" sign for proper installation, operation, and maintenance of the equipment.

General Precaution on Environment

- Do not keep or operate the equipment in the environment listed below.

	Avoid placing in an area exposed to moist. Do not touch the equipment with wet hand.		Avoid exposure to direct sunlight
	Avoid placing in an area where there is a high variation of temperature. Operating temperature ranges from 10(C to 40(C. Operating humidity ranges from 30% to 85%.		Avoid in the vicinity of Electric heater
	Avoid placing in an area where there is an excessive humidity rise or ventilation problem.		Avoid placing in an area where there is an excessive shock or vibration.
	Avoid placing in an area where chemicals are stored or where there is danger of gas leakage.		Avoid being inserted dust and especially metal material into the equipment
	Do not disjoint or disassemble the equipment. We take no responsibility for it.		Power off when the equipment is not fully installed. Otherwise, equipment could be damaged.

CAUTIONS

Before Installation

Compatibility is critical to safe and effective use of this device. Please contact your local sales or service representative prior to installation to verify equipment compatibility.

Defibrillator Precaution

Patient signal inputs labeled with the CF and BF symbols with paddles are protected against damage resulting from defibrillation voltages. To ensure proper defibrillator protection, use only the recommended cables and lead wires.

Proper placement of defibrillator paddles in relation to the electrodes is required to ensure successful defibrillation.

Disposables

Disposable devices are intended for single use only. They should not be reused as performance could degrade or contamination could occur.

Disposal

At the end of its accessories, must be disposed of in this manual, as well as its accessories, must be disposed of in compliance with the guidelines regulating the disposal of such products. If you have questions concerning disposal of products, please contact GIMA SPA or its representatives.

Electrocute Precautions

To prevent skin burns, apply electrocute electrodes as far as possible from all other electrodes, a distance of at 15 cm/6 in. is recommended.

EMC

Magnetic and electrical fields are capable of interfering with the proper performance of the device. For this reason make sure that all external devices operated in the vicinity of the monitor comply with the relevant EMC requirements. X-ray equipment or MRI devices are possible source of interference as they may emit higher levels of electromagnetic radiation.

Also, keep cellular phones to other telecommunication equipment away from the monitor.

CAUTIONS

Instruction for Use

For continued safe use of this equipment, it is necessary that the instructions are followed. However, instructions listed in this in no way supersede established medical practices concerning patient care.

Loss of Data

Should the monitor at any time temporarily lose patient data, the potential exists that active monitoring is not being done. Close patient observation or alternate monitoring devices should be used until monitor function is restored.

If the monitor does not automatically resume operation within 60 seconds, power cycle the monitor using the power on/off switch. Once monitoring is restored, you should verify correct monitoring state and alarm function.

Maintenance

Regular preventive maintenance should be carried out annually (Technical inspections). You are responsible for any requirements specific to your country.

MPSO

The use of a multiple portable socket outlet (MPSO) for a system will result in an enclosure leakage current equal to the sum of all individual earth leakage currents of the system if there is an interruption of the MPSO protective earth conductor. Do not use an additional extension cable with the MPSO as it will increase the chance of the single protective earth conductor interruption.

Negligence

GIMA SPA does not assume responsibility for damage to the equipment caused by improperly vented cabinets, improper or faulty power, or insufficient wall strength to support equipment mounted on such walls.

NOTES

Power Requirements

Before connecting the device to the power line, check that the voltage and frequency. Ratings of the power line are the same as those indicated on the unit's label. If this is not the case, do not connect the system to the power line until you adjust the unit to match the power source. In U.S.A, if the installation of this equipment will use 240V rather than 120V, the source must be a center-tapped, 240V, single-phase circuit.

Restricted Sale

U.S.A federal law restricts this device to sale by or on the order of a physician.

Supervised Use

This equipment is intended for use under the direct supervision of a licensed health care practitioner.

Ventilation Requirements

Set up the device in a location which affords sufficient ventilation. The ventilation openings of the device must not be obstructed. The ambient conditions specified in the technical specifications must be ensured at all times.

·Put the monitor in a location where you can easily see the screen and access the operating controls.

·This product is protected against the effects of cardiac defibrillator discharges to ensure proper recovery, as required by test standards. (the screen may blank during a defibrillator discharge but recovers within second as required by test standards.)

Reference Literature

Medical Device Directive 93/42/EEC

EN 60601-1/1990 +A1: 1993 +A2 : 1995 : Medical electrical equipment.

General requirements for safety

EN 60601-1-1/9. 1994 +A1 12.95: General requirements for safety.

General Precaution on Electric Safety

Warning
Check the item listed below before operating the equipment.

1. Be sure that AC power supply line is appropriate to use. (AC100 - 240V)
2. Be sure that the power source is the one supplied from GIMA SPA.. (DC18V, 2.5A)
3. Be sure that the entire connection cable of the system is properly and firmly fixed.
4. Be sure that the equipment is completely grounded. (If not, there might be the problem occur in the product.)
5. The equipment should not be placed in the vicinity of electric generator, X-ray, broadcasting apparatus to eliminate the electric noise during operation. Otherwise, it may cause incorrect result.

Note
The Equipment should be placed far from generator, X-ray equipment, broadcasting equipment or transmitting wires, so as to prevent the electrical noises from being generated during the operation, When these devices are near the Equipment, it can produce inaccurate measurements. For B3, both independent circuit and stable grounding are essentially required. In the event that the same power source is shared with other electronic equipment, it can also produce inaccurate output.

Warning
Do not contacts with the patient while operate the machine It may cause serious danger to the users. Use only the provided cable.

Warning
In case the Equipment does not operate as usual or damaged, do not use on patient, and contact to the medical equipment technician of the hospital or the equipment supply division.

Note
B3 is classified as follows: - B3 classifies as Class **I,** BF **&** CF concerning electric shock. It is not proper to operate this Equipment around combustible anesthetic or dissolvent. - Noise level is B class regarding IEC/EN 60601-1 and the subject of Nose is B level concerning IEC/EN60601-1-2.

Equipment Connection

Caution
In the hospital, doctors and patients are exposed to dangerous, uncontrollable compensating currents. These currents are due to the potential differences between connected equipment The safety solution to the problem is accomplished with EN60601-1;1993.

Biocompatibility

When used as intended, the parts of the product described in this operator manual, including accessories that come in contact with the patient during the intended use, fulfill the biocompatibility requirements of the applicable standards. If you have questions about this matter, please contact GIMA SPA. or its representatives.

Maintenance and Washing Equipment Connection

Using various methods can clean B3 and its accessories. Please follow the methods mentioned below to avoid unnecessary damage or contamination to the Equipment.

We do not repair with free of charge regardless of warranty period if it is contaminated or damaged with using dangerous material not designated for washing.

Cleaning Applied Parts

Cables and Leadwires

CAUTION
Do not use acetone or ketone solvents for cleaning; do not use an autoclave or steam cleaner.

Cables and leadwires can be cleaned with a warm, damp cloth and mild soap, or isopropyl alcohol wipes. For more intensive disinfecting (near sterile) Ethylene Oxide (ETO) is acceptable but will reduce the useful lifetime of the cable or leadwire.

CAUTION
The decision to sterilize must be made per your institution's requirements with an awareness of the effect on the integrity of the cable or leadwire.

Note
The Equipment needs safety inspection once a year. Please refer to user's guide or service manual for the examine objects.

Please check carefully both frame and sensor, after cleaning the Equipment, Do not use the equipment that is worn out or damaged.

At least once a month, clean and wipe off the frame by using the soft cloth after wetting it with water and alcohol. Do not use lacquer, thinner, ethylene, and oxidizer which may leads damage to the equipment.

Make sure both cables and accessories are free of dust or contaminants, and wipe them off with soft cloth wetted with warm water (40°), and at least once a week, clean them by using the clinical alcohol.

Do not submerge the accessories under any liquid or detergent. Also, make sure any liquid not to penetrate into the Equipment or probe.

Caution
Do not dispose single use probe to any hazard place, Always think about environmental contamination.

Caution
There is back-up battery on board inside system. When users dispose this battery, Please waste proper place for environmental protection.

Warning
Check the electrodes of batteries before changing them.

· Operate B3 with internal electric power supply when unsure of external ground connection or installation occur.
· Remove the 1st Battery when not using equipment for a while without any damage.

For other applied parts such as temperature sensors, pulse oximetry probes, and NBP cuffs, you must consult the manufacturer for cleaning, sterilization, or disinfecting methods.

1.3 Product Components

Product Outline

B3 monitor is a product used for monitoring biological information and occurrence of a patient. Main function ns of the product include displaying information such as ECG, respiration, SpO2, NIBP and temperature on its LCD screen and monitoring parameter, and alarming. It also prints out waves and parameters via a printer.

Principal Characters of Product

B3 is a small-size multifunctional monitoring equipment for a patient designed to an easy usage during movement. It features devices for auto power supply (DC 10V-16V) and DC power supply (DC 18V) as well as installing its handle to the patient's bed. The equipment also measures major parameters such as ECG, SpO2, NIBP, temperature and pulse, displaying it on a 7-inch color LCD screen. It also enables users to check waves and parameters and other vital signs of a patient via the 58mm thermal printer and monitor the patient by the remote-controlled alarm system. It also enables to build a central monitoring system by linking devices used for separate patients so that one can monitor several patients at a time.

Warning
Use only the supplement accessories provided by us. Otherwise, patient and user may exposed to danger.

Warning
BEFORE USE — Before putting the system into operation visually inspect all connecting cables for signs of damage. Damaged cables and connectors must be replaced immediately. Before using the system, the operator must verify that it is in correct working order and operating condition. Periodically, and whenever the integrity of the product is in doubt, test all functions.

Product Configuration

1. Main body of B3 Monitor	1 EA
2. 3-Lead Patient Cable	1EA (3CBL-400, 3WIRE-400)
3. Disposable electrodes	10 EA (ECGSENS-400)
4. NIBP tubing (3M long)	1EA (NBPCBL-400)
5. Adult cuff (25-35 Cm)	1EA (ACUFF-400)
6. SpO2 sensor extension cable (2M)	1EA (SPCBL-400)
7. SpO_2 Probe	1 EA (SPASENS-400)
8. DC Adaptor (MW160 made in AULT Co., Ltd.)	1 EA

Option Product

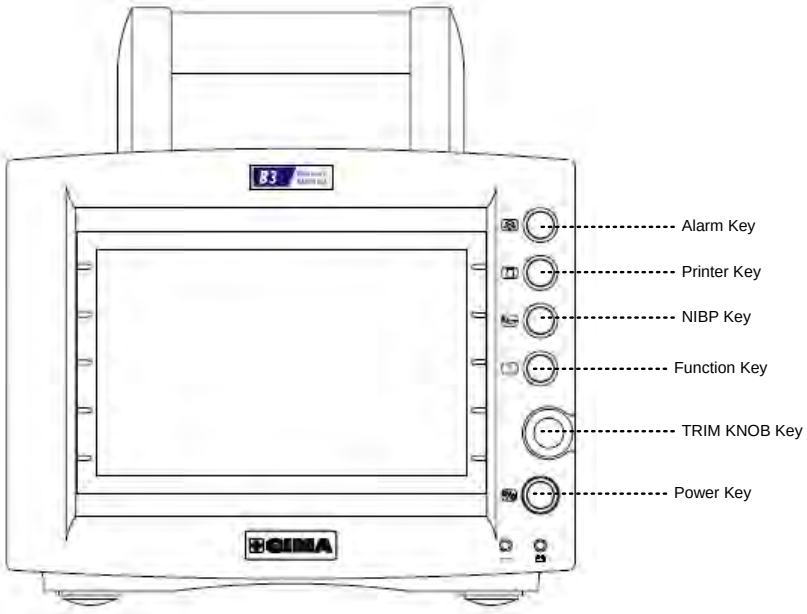
1. Temperature (TEMPSENS-400)

Warning
In order to avoid electrical shock, do not open the cover. Disassembling of the equipment should be done only by the service personnel authorized by GIMA SPA.

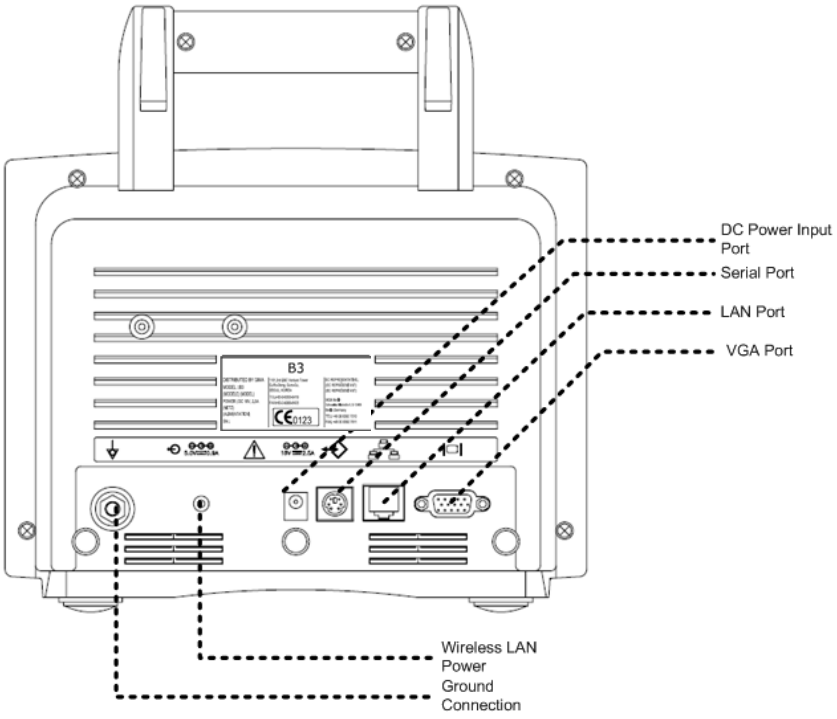
Warning
Users must pay attention on connection any auxiliary device via LAN port or nurse calling. Always consider about summation of leakage current, please check if the auxiliary device is qualified by IEC 60601-1, or consult your hospital biomedical engineer.

Product Body Configuration

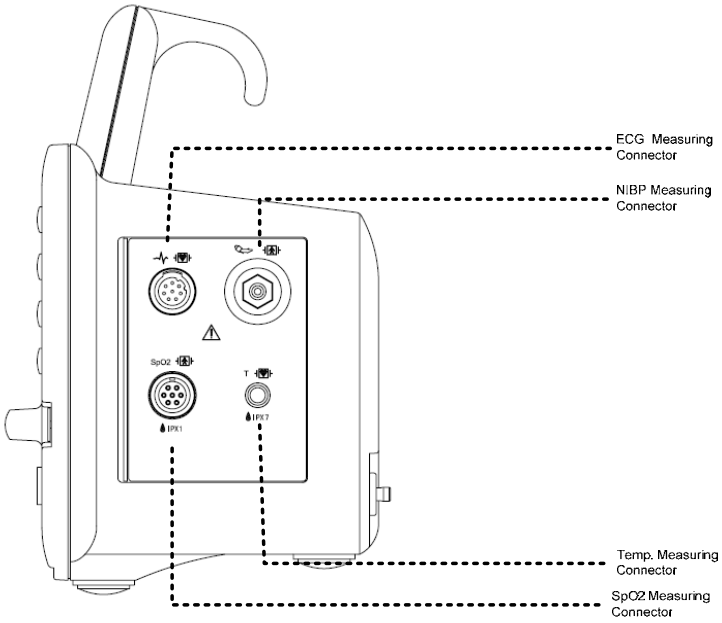
FRONT



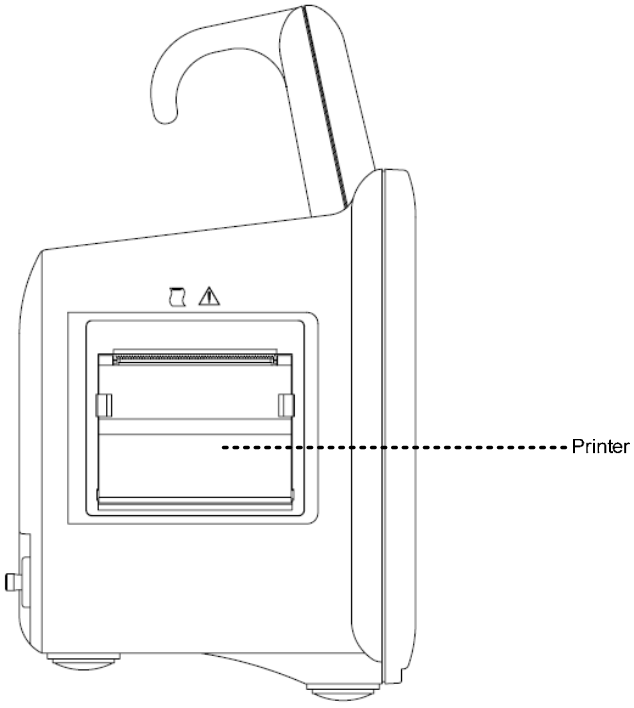
BACK



Right Side



Left Side



Accessories

ECG Cable +
Extension Cable

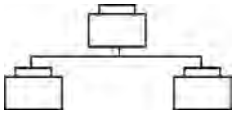
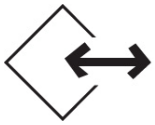
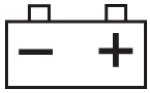
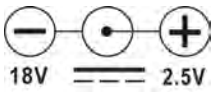
SpO_2 Cable +
Extension Cable

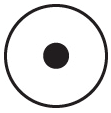
NIBP Cuff+
Extension hose

Temperature
sensor (Option)

Equipment Sign

	ATTENTION : Consult accompanying documents
	TYPE CF APPLIED PART : Insulated (floating) applied part suitable for intentional external and internal application to the patient including direct cardiac application. "Paddles" outside the box indicate the applied part is defibrillator proof. Medical Standard Definition : F-type applied part(floating/insulated) complying with the specified requirements of IEC 60601-1/UL 2601-1/CSA 601.1 Medical Standards to provide a higher degree of protection against electric shock tan that provided by type CF applied parts.
	TYPE BF APPLIED PART : Insulated (floating) applied part suitable for intentional external and internal application to the patient excluding direct cardiac application. "Paddles" outside the box indicate the applied part is defibrillator proof. Medical Standard Definition : F-type applied part (floating/insulated) complying with the specified requirements of IEC 60601-1/UL 2601-1/CSA 601.1 Medical Standards to provide a higher degree of protection against electric shock than that provided by type BF applied parts.

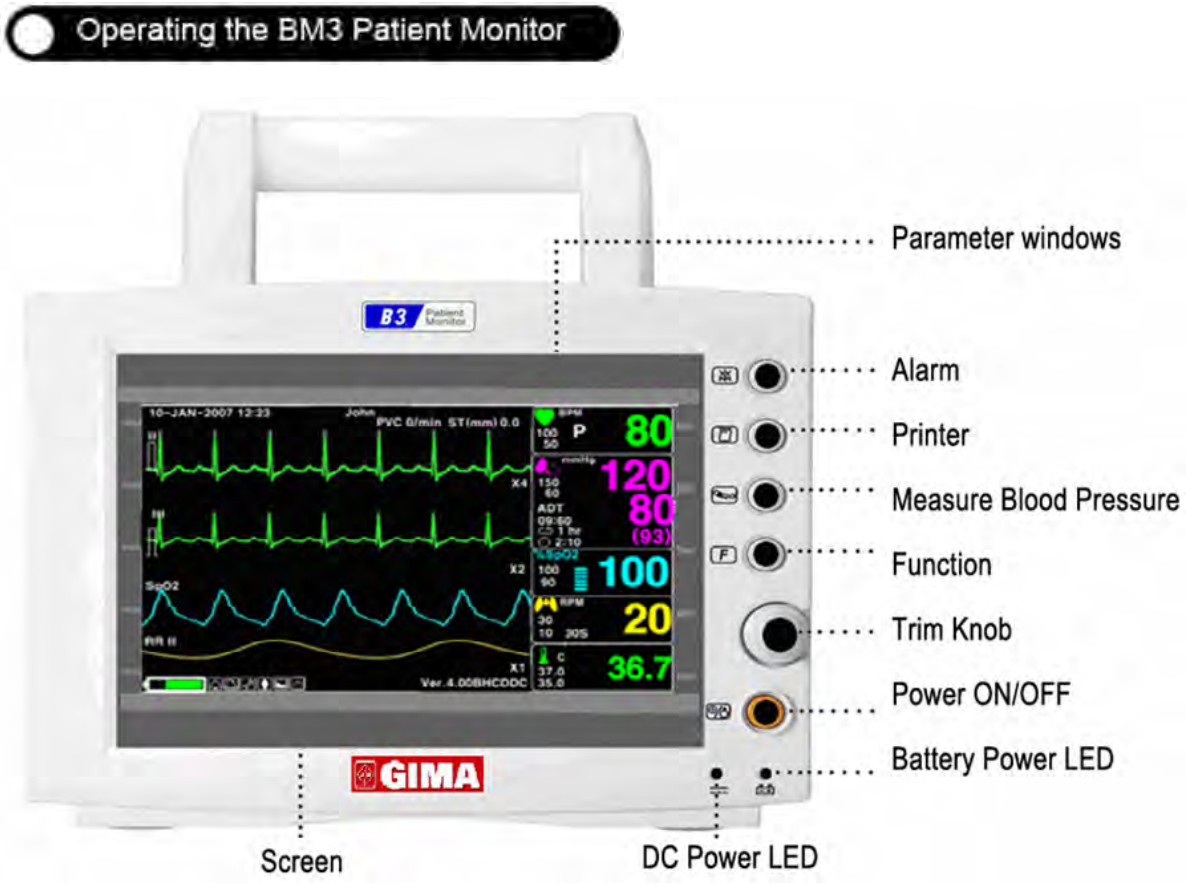
	Ground
	Printer
	Serial Port
	**LAN Port**
	**AUX Connector Port**
	DC Input Indicator
	**Battery Operation Indicator**
	**DC Input Connector**

	NIBP
	Temperature
	Function
	**Power on**
	Power off
	Respiration
	ECG
	Heart Pulse

1.4 Function and Key

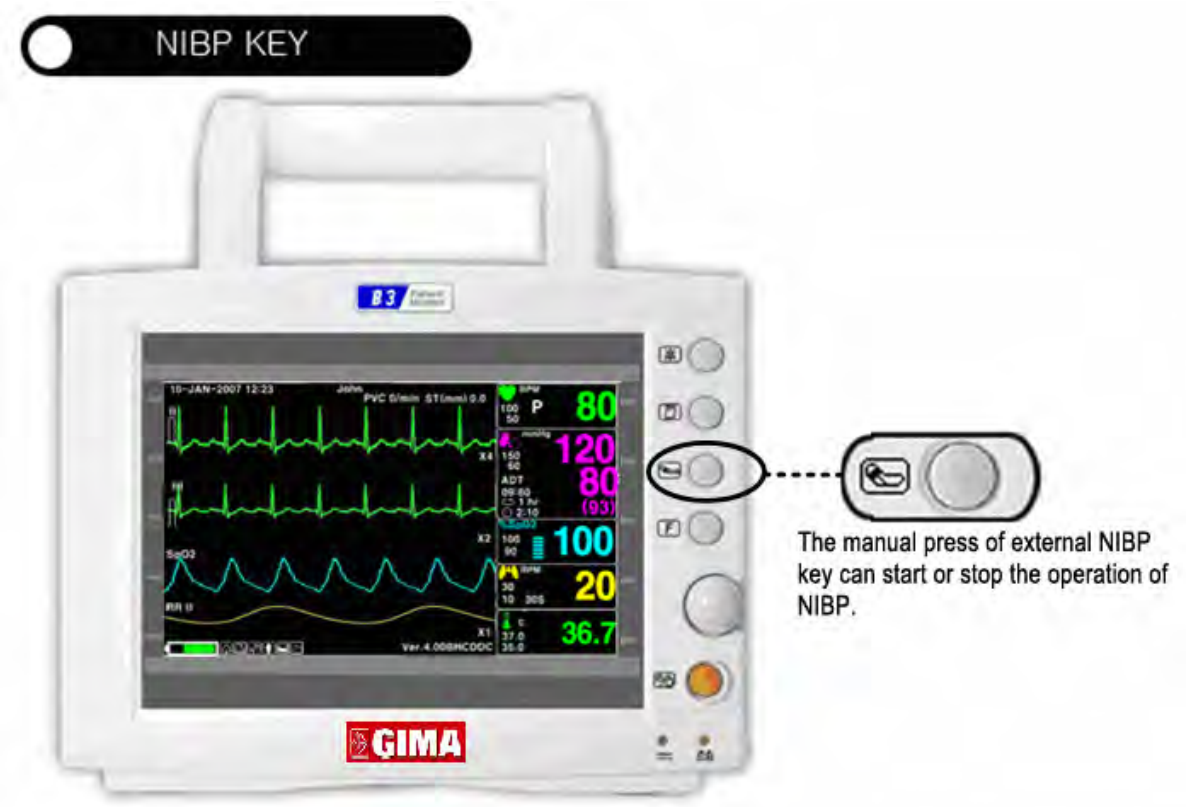
External Function

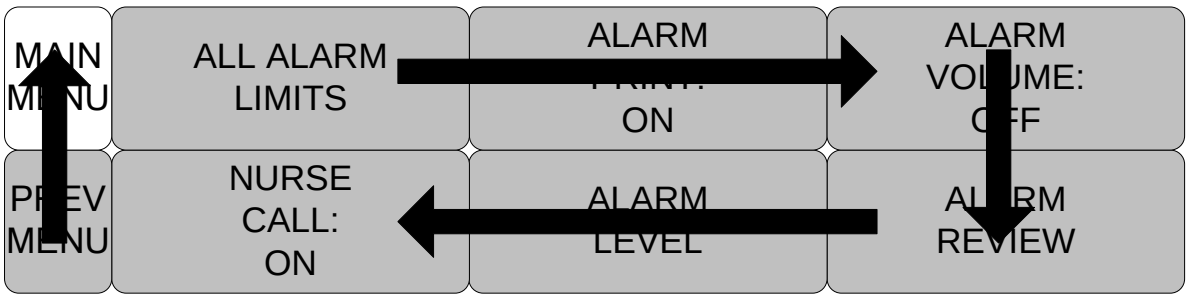
The front panel of this product consists of an LCD screen and five function keys and one trim knob.



Operation Key

1. Power : Switches on and off the Power.
2. Function Key
3. Blood Pressure：Manually completes measuring blood pressure.
4. Printer：Prints out the waves selected from the menu until the key is pressed to stop.
5. Alarm： Stop alarm sound.
   First press stops the current alarm for one minute
   Second press stops the all alarm for five minutes.
   Third press makes the alarm back to the original setting.
6. Trim Knob：This key is used to select menu by turning it clock or anticlockwise to move cursors.


NIBP KEY
B3
GIMA
The manual press of external NIBP key can start or stop the operation of NIBP.

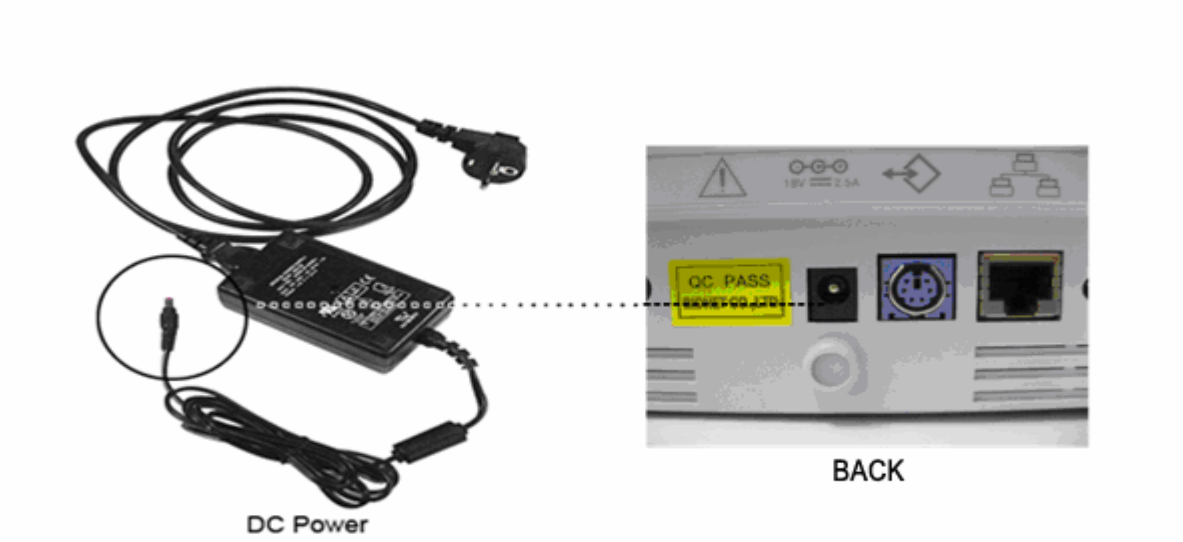

MAIN MENU
ALL ALARM LIMITS
ALARM
ON
ALARM VOLUME: OFF
PREV MENU
NURSE CALL: ON
ALARM LEVEL
ALARM REVIEW

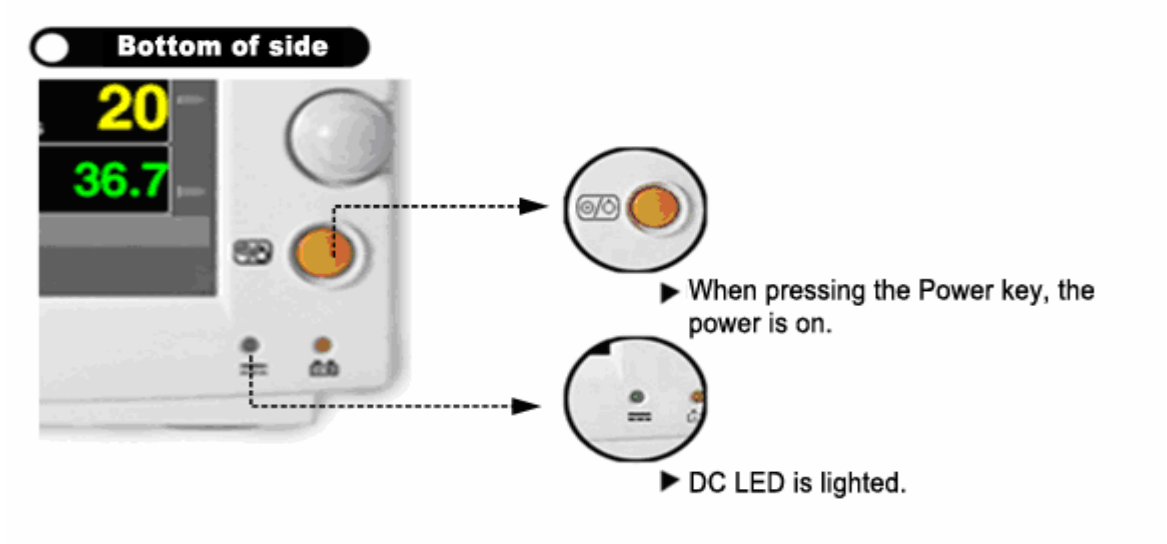
1.5 Standard Power Supply Application

DC Power

DC Power LED is lighted on when the DC Power is plugged into the inlet at the back of the product.

A press of power key makes the machine ready for use.





Warning
This equipment must only be connected to a supply mains with protected earth.

1.6 Battery Power Supply Application

Battery power can be supplied for enabling a portable use or a use during DC power failure.

Operation

1. Battery Power LED is lighted on when the machine is in use.

2. The DC/battery power is only sustainable for 1 hour.

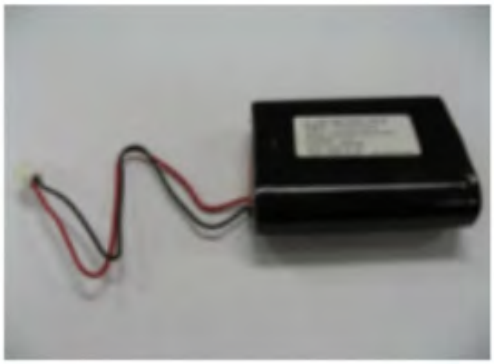
3. Battery is automatically charged when the machine is connected to DC Power Supply. Battery LED is lighted on after blinking.

4. The charging status of the batteries is displayed with 5 green boxes, each indicating a different charging

. (0% -> 25% -> 50% -> 75% -> 100%)

- Battery: LS1865L2203S1PMXZ(11.1V - 2200mA, Li-ion)

The Lithium-Ion battery is a rechargeable battery containing Lithium-Ion cells. Each battery contains an integrated electronic fuel gauge and a safety protection circuit.



5. The discharge condition of battery is indicated with on of 5 yellow boxes, each box showing a different level of charge available.

.

(100% -> 75% -> 50% -> 25% -> 0%)

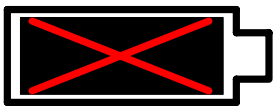
When the battery power remains 25%, the message of "Low Battery" is displayed. The power is automatically cut off after 5 minutes from the appearance of the message. The machine will no longer operate when the "Low Battery" indication is on. Charge the batteries with the power adaptor, which GIMA SPA. provided.

-Battery charging time: More than 6 hours

-Continuous battery use time: Lowest 1 hour to highest 2 hours continuous use (buffering)

Warning
Check the electrodes of batteries before charging them.

6. Battery status indication: When battery is apart from equipment and out of order, it is shown by a red `X' as shown below.



7. Automobile power supply: When an automobile power uses 12V~15V, the battery indication disappears and the "CAR" indication is active.

Display of automobile power

Note
Battery is not charged when the automobile power is used.

The Impact of Lithium-Ion Battery Technology on the Battery

The following are the key points you should know about Lithium-Ion battery technology:

The battery will discharge on its own, even when it is not installed in a monitor. This discharge is the result of the Lithium-Ion cells and the bias current required for the integrated electronics.

By the nature of Lithium-Ion cells, the battery will self-discharge.

The self-discharge rate doubles for every 10°C (18°F) rise in temperature.

The capacity loss of the battery degrades significantly at higher temperatures.

As the battery ages, the full-charge capacity of the battery will degrade and be permanently lost. As a result, the amount of charge that is stored and available for use is reduced.

Conditioning Guideline

the battery in the monitor full charged and discharged every six months and condition it using the battery charger.

Storage Guideline

Store the battery outside of the monitor at a temperature between 20°C to 25°C (68°F to 77°F).

When the battery is stored inside a monitor that is powered by an AC power source, the battery cell temperature increases by 15°C to 20°C (59°F to 68°F) above the room's ambient temperature. This reduces the life of the battery.

When the battery is stored inside a monitor that is continuously powered by an AC power source and is not powered by battery on a regular basis, the life of the battery may be less than 12 months. GIMA SPA. recommends that you remove the battery and store it near the monitor until it is needed for transport.

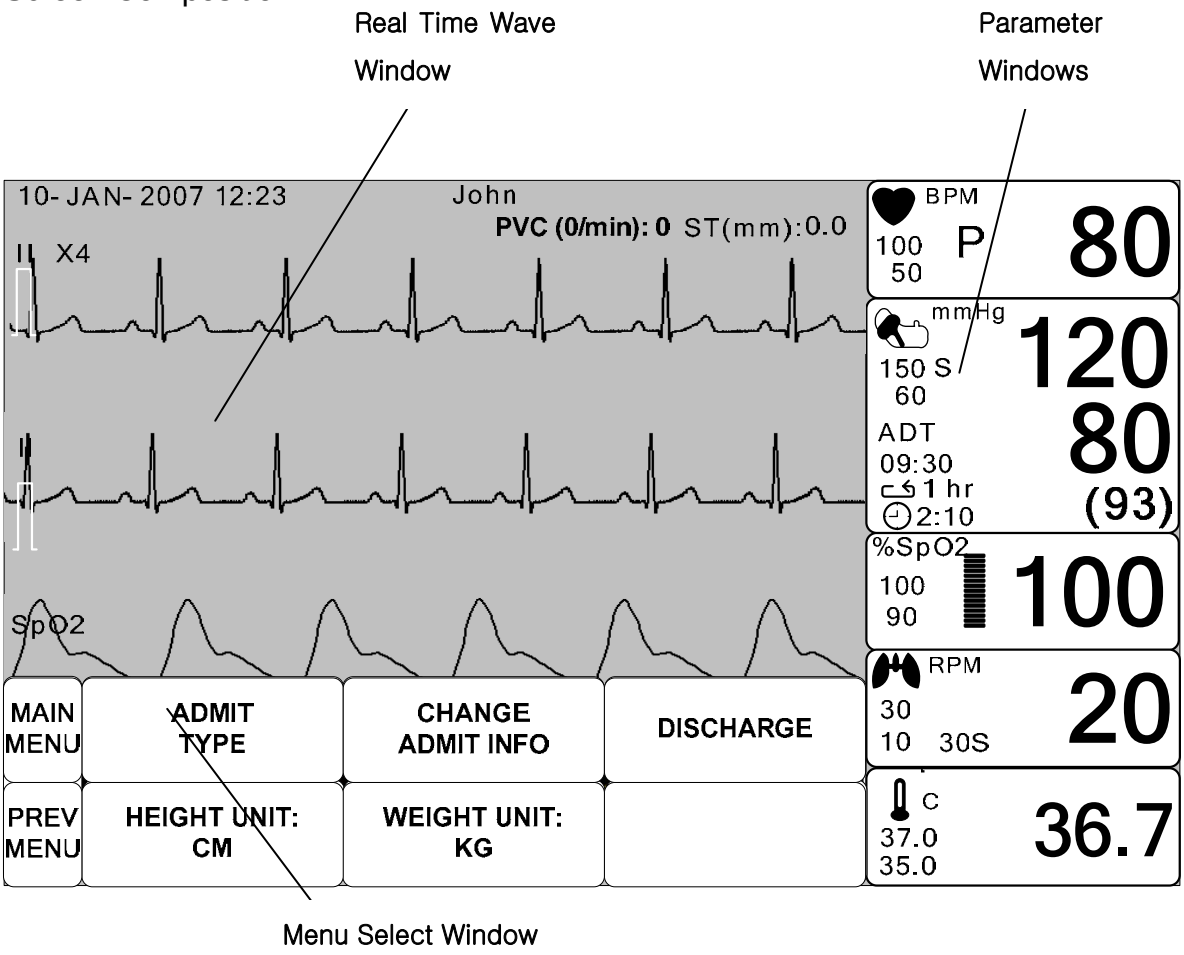
How to Recycle the Battery

When the battery no longer holds a charge, it should be replaced. The battery is recyclables. Remove the old battery from the monitor and follow your local recycling guidelines.

WARNING
EXPLOSION HAZARD — DO NOT incinerate the battery or store at high temperatures. Serious injury or death could result.

1.7 General Manu Operation

Screen Composition

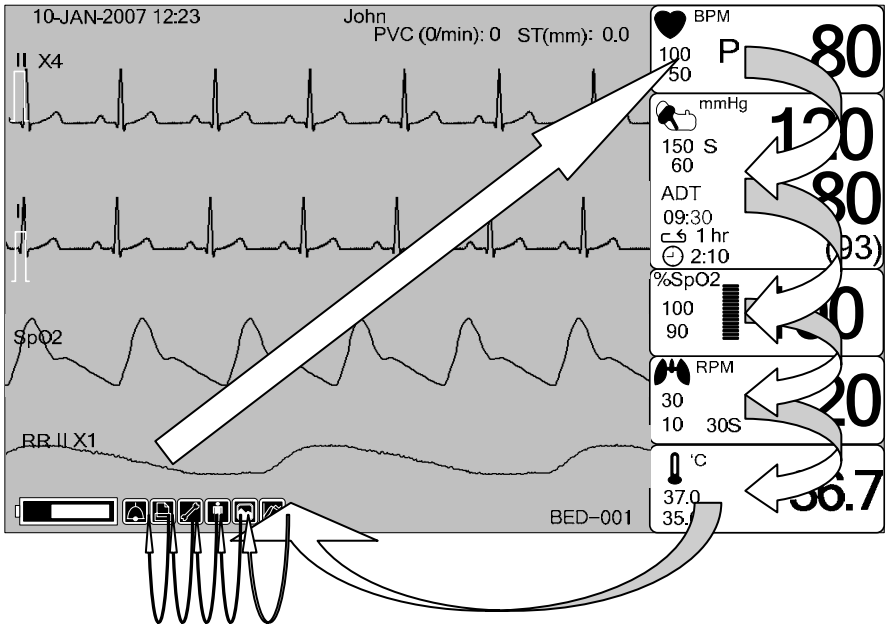


Real Time Wave Window：Displays measured results by up to three waves.

Menu Select Window：Menus appear when they are activated..

Parameter Window：Measured and setup data are displayed in five windows.

Menu Selection



Turn or press the knob.

When the Trim Knob Key is turned, menus are selected in the order indicated above. The above screen shows that the MORE menus is selected. The menus move to the right in the order of MORE MENU → ECG → NIBP →SpO_2 → RESP → TEMP. An inactivated window is jumped off.

Menu Composition

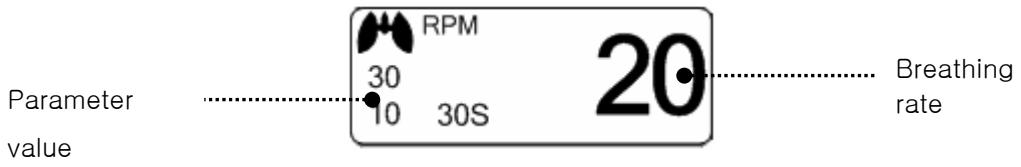
More Menu Window

When the additional menu is selected it will set and cancel the functions.

MAIN MENU	DISPLAY		USER SERVICE
PREV MENU		DEMO: ON	MAKER SERVICE

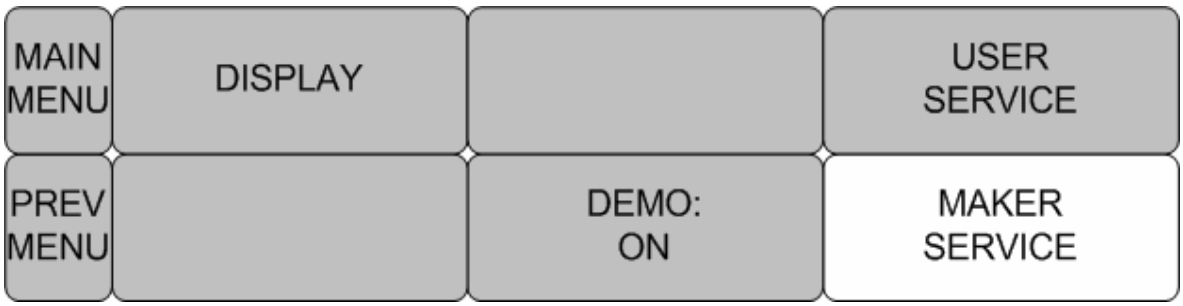
Numerical value sign widow

This window displays a measured parameter, function setup, and the boundary of parameter values.



Menu selection by using Trim Knob key

As the key is turn to the right, the menu selection moves clockwise. As the key is turn to the left, the menu selection moves counterclockwise. The menu selection is activated when you depress Trim Knob key.

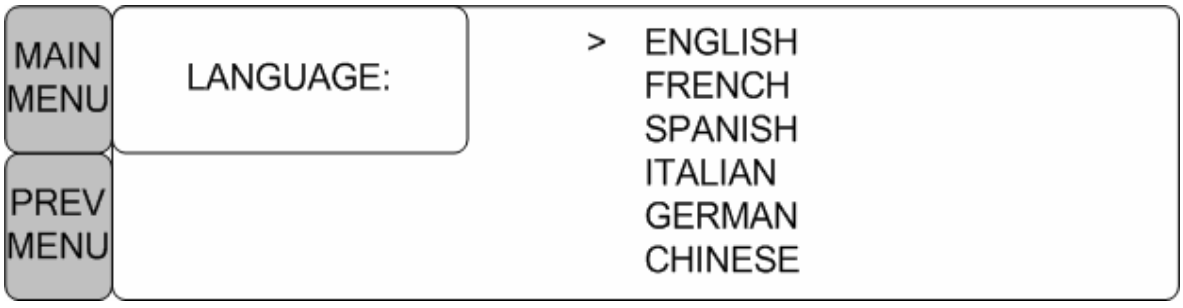


Menu selection with arrows

Upward Movement: Turns the Trim Knob key to the left.

Downward Movement: Turns the Trim Knob key to the right.

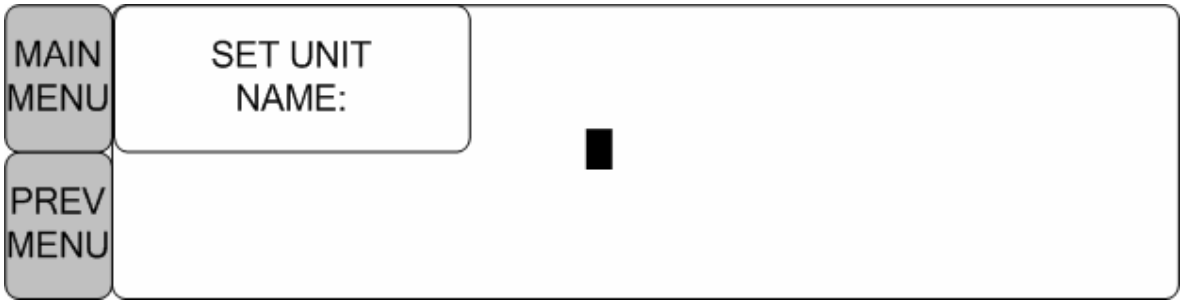
Selection is made by pressing the Trim Knob key. One comes out of the menu after the selection.



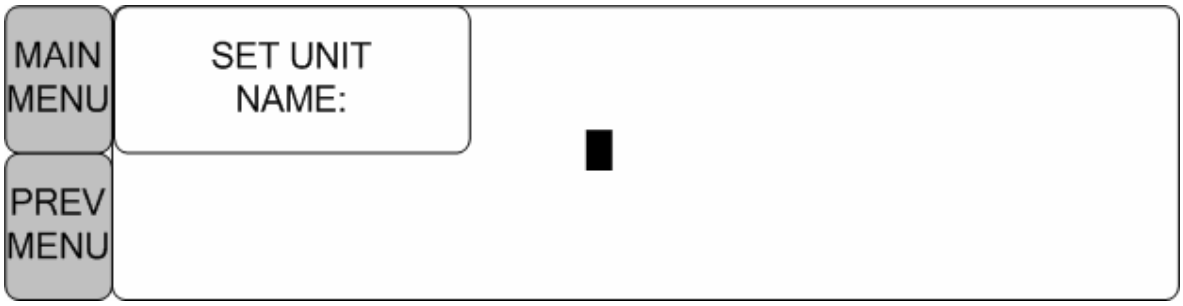
When moving the within quadrilateral, the letter reverses, and the numeric value reflects immediately.

Word feature menu

The following figure shows the screen where the word sequence menu is activated within the word sequence correction menu. Here, the cursor moves over the words when the Trim Knob key is turned in the clockwise direction.



The above figure shows how the cursor moves on the screen. The cursor moves according to the direction the Trim Knob Key is turned. Press the Trim Knob key if you want to change a letter currently on the screen.

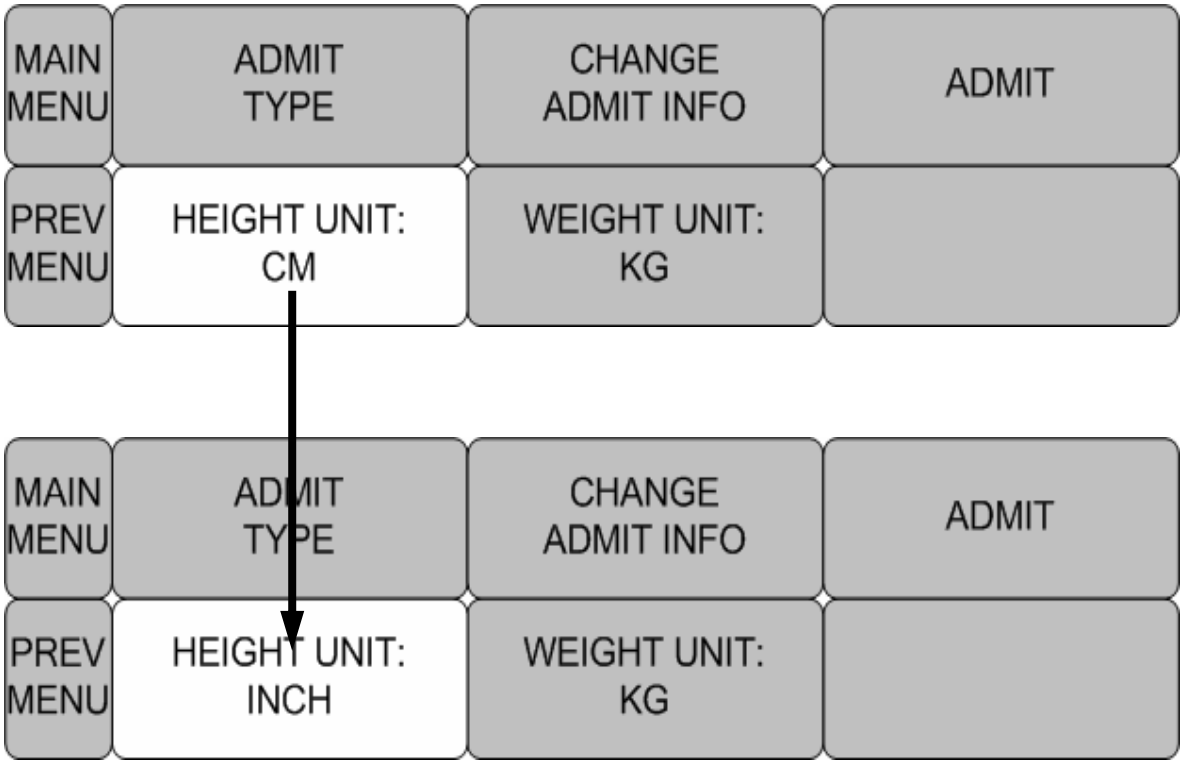


The above figure shows how the cursor is selected to change a letter. Right-hand turning of the Trim Knob Key makes it possible to select in the order of 0-9,A-Z, and a blank, while left-hand turning makes the movement in the opposite direction. Once a letter or a number is selected, the screen comes back to the condition where the same process of selection can be made. One may move to

the menu item in the left of the screen to end the process, which is completed by pressing Trim Knob Key. After completion, the screen comes back to the earlier picture.

Operation menu

The setup value changes without a selection when the menu is moved.



2. PATIENT/DATA MANAGEMENT

2.1 ADMIT

CHANGE ADMIT INFO

DISCHARGE

HEIGHT

WEIGHT

2.2 ALARM

ALL LIMITS

ALARM PRINT

ALARM VOLUME

ALARM LEVEL

ARRHYTH LEVEL

ALARM REVIEW

ALARM LIST

SAVE ALARM LEVEL

NURSE CALL

Additional setups are made foe each parameter function. One can make an overall setup for the entire monitor system.

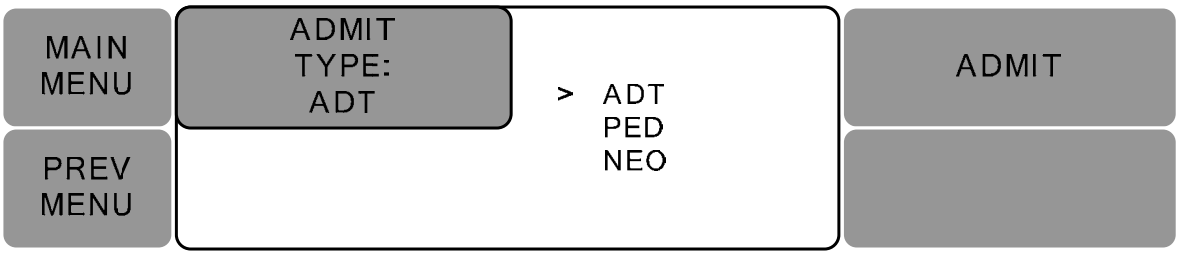
2.1 ADMIT

CHANGE ADMIT INFO
DISCHARGE
HEIGHT UNIT
WEIGHT UNIT

ADMIT TYPE

Set the exercise environment of equipment in discharge status.

ADU : ADULT ICU // PED: PEDIATRIC ICU // NEO : NEONATE ICU



CHANGE ADMIT INFO

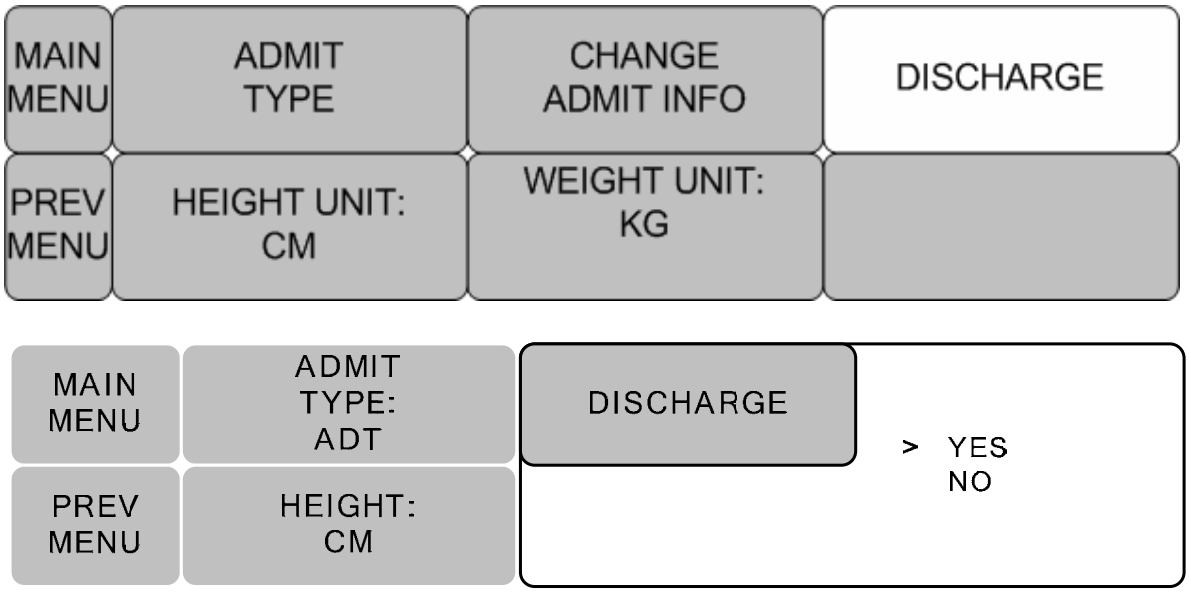
Last and first name (11 letters for each), sex (male or female), date of birth, weight, height, and patient ID (13 characters)

MAIN MENU	ADMIT TYPE	CHANGE ADMIT INFO	DISCHARGE
PREV MENU	HEIGHT UNIT: CM	WEIGHT UNIT: KG	

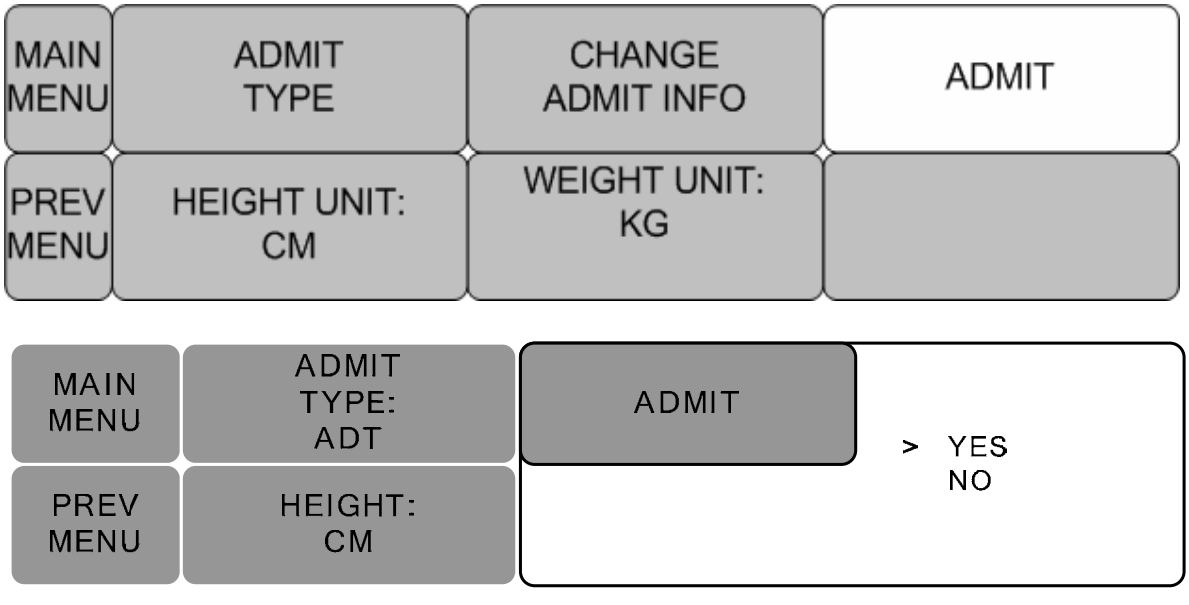
CHANGE ADMIT INFORMATION	
RETURN	**CONTENTS**
LAST NAME	JOHN
FIRST NAME	WASHINGTON
PATIENT ID	BM-001
SEX	MALE
BIRTH DATE	01 – JAN - 2007
AGE	30
HEIGHT	180cm
WEIGHT	80kg

DISCHARGE

Patient information and all numbers change to standard, and the screen displays, "ALL ALARMS OFF ADMIT PATIENT TO ACTIVE ALARMS."



ADMIT



HEIGHT

Unit of height is set as Cm / Inches.

MAIN MENU	ADMIT TYPE	CHANGE ADMIT INFO	ADMIT
PREV MENU	HEIGHT UNIT: CM	WEIGHT UNIT: KG	

MAIN MENU	ADMIT TYPE	CHANGE ADMIT INFO	ADMIT
PREV MENU	HEIGHT UNIT: INCH	WEIGHT UNIT: KG	

WEIGHT

Unit of weight is set as Kg / LBS.

MAIN MENU	ADMIT TYPE	CHANGE ADMIT INFO	ADMIT
PREV MENU	HEIGHT UNIT: INCH	WEIGHT UNIT: KG	

MAIN MENU	ADMIT TYPE	CHANGE ADMIT INFO	ADMIT
PREV MENU	HEIGHT UNIT: INCH	WEIGHT UNIT: LBS	

2.2 ALARM

Alarm is divided into two, alarm for the patient's condition and for the product's condition.

The patient's alarm sounds when the diagnostic functions (ASYSTOLE, VTAC/VFIB, and VTAC) are detected. Each alarm sound differs in order in order and volume according to the levels of HIGH, MEDIUM, LOW and MESSAGE.

HIGH		-5	≡	300	≡		
MEDIUM		-3	≡	300	≡		
LOW		-1	≡	300	≡		
MESSAGE			≡	300	≡		

: Alarm sounds

≡ 300 ≡ : Number flashes

: Waves are printed out

: Alarm lamp flashes

Alarm for the Product

The machine gives alarm sounds for its system with a related message flashing.

LOW -1 ≡ Alarm Text ≡

ALARM LIMITS：The machine enables one to see and change the limits of alarm for all parameter functions.

ALARM PRINT：with an ON/OFF setup, the related information is printed out whenever an alarm is given.

ALARM VOLUME：volume of each alarm can be adjusted in 10 step.

ALARM LEVEL：Priority of each parameter alarm can be set up.

ALARM REVIEW： Shows the priority order information for all alarms of each measurement.

NURSE CALL： Set the ON/OFF feature of the NURSE CALL.

MAIN MENU	ALL ALARM LIMITS	ALARM PRINT: ON	ALARM VOLUME: OFF
PREV MENU	NURSE CALL: ON	ALARM LEVEL	ALARM REVIEW

It is able to see all the alarm range and change of measurement function.

ALL LIMITS

MAIN MENU	ALL ALARM LIMITS	ALARM PRINT: ON	ALARM VOLUME: OFF
PREV MENU	NURSE CALL: ON	ALARM LEVEL	ALARM REVIEW

ALL ALARM LIMIT

RETURN	UNITS	LOW	HIGH
HR	BPM	50	150
SPO2	%	90	100
PR	BPM	50	150
RESP	RPM	10	30
RESP-A	SEC	0	20
NIBP-S	mmHg	80	200
NIBP-M	mmHg	60	140
NIBP-D	mmHg	20	120
TEMP	℃	30.0	42.0

ALARM PRINT

Set ON/OFF functions automatically. When the alarm is activated the corresponding information is printed on heat sensitive paper.

MAIN MENU	ALL ALARM LIMITS	ALARM PRINT: ON	ALARM VOLUME: OFF
PREV MENU	NURSE CALL: ON	ALARM LEVEL	ALARM REVIEW

ALARM VOLUME

Set the alarm volume to be set at 10 grades.

MAIN MENU	ALL ALARM LIMITS	ALARM PRINT: OFF	ALARM VOLUME: OFF
PREV MENU	NURSE CALL: ON	ALARM LEVEL	ALARM REVIEW

MAIN MENU	ALARM VOLUME :	> OFF	60%
PREV MENU		10%	70%
		20%	80%
		30%	90%
		40%	100%
		50%	

ALARM LEVEL

Set the order of priority in each alarm.

MAIN MENU	ALL ALARM LIMITS	ALARM PRINT: ON	ALARM VOLUME: OFF
PREV MENU	NURSE CALL: ON	ALARM LEVEL	ALARM REVIEW

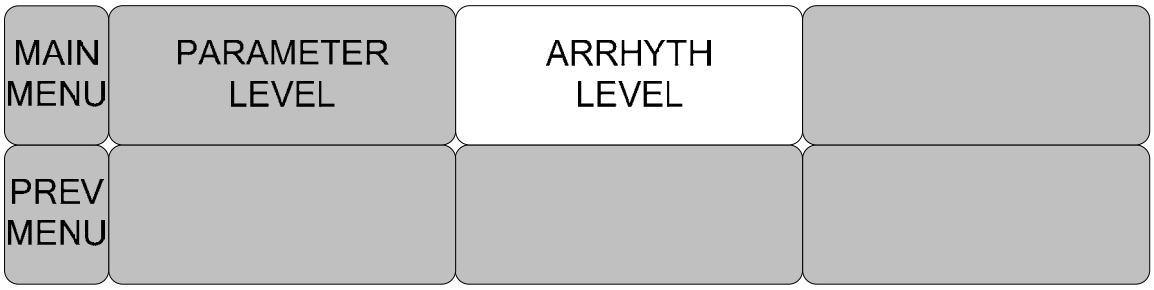
MAIN MENU	PARAMETER LEVEL	ARRHYTH LEVEL	
PREV MENU			

PARAMETER LEVEL

PARAMETER ALARM LEVEL	
RETURN	ALARM LEVEL
HR	MEDIUM
SPO2-%	MEDIUM
SPO2-R	LOW
RESP	MESSAGE
RESP-A	MESSAGE
NIBP-S	MEDIUM
NIBP-M	MEDIUM
NIBP-D	MEDIUM
TEMP	MESSAGE
LEAD FAULT	MESSAGE
LOW BATTERY	MESSAGE

ARRHYTH LEVEL

One can set up priorities when he or she uses the alarm for the diagnostic function.



ARRHYTHMIA ALARM LEVELS	
RETURN	ALARM LEVEL
ASYSTOLE	HIGH
VTAC/VFIB	HIGH
VTAC	HIGH

ALARM REVIEW

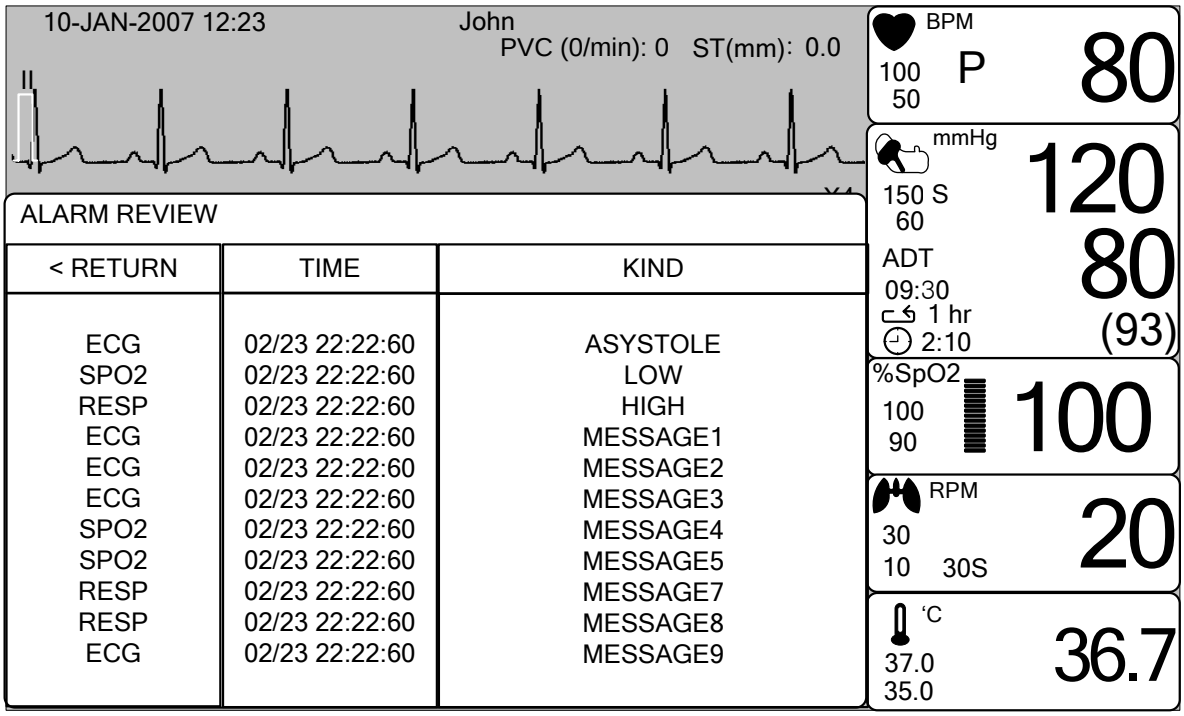
After an alarm is triggered the alarms and data wave pattern can be reviewed. Set up for priority of each parameter alarm.

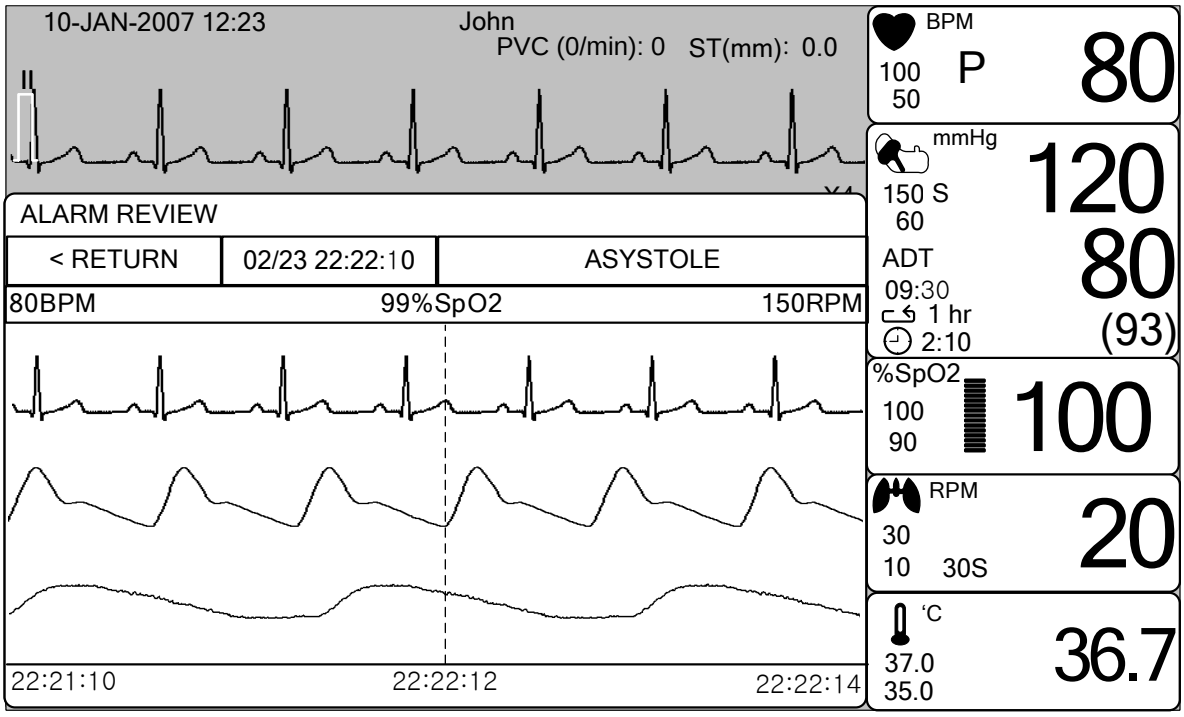
MAIN MENU	ALL ALARM LIMITS	ALARM PRINT: ON	ALARM VOLUME: OFF
PREV MENU	NURSE CALL: ON	ALARM LEVEL	ALARM REVIEW

MAIN MENU	ALARM LIST	SAVING CONDITION	
PREV MENU			

ALARM LIST

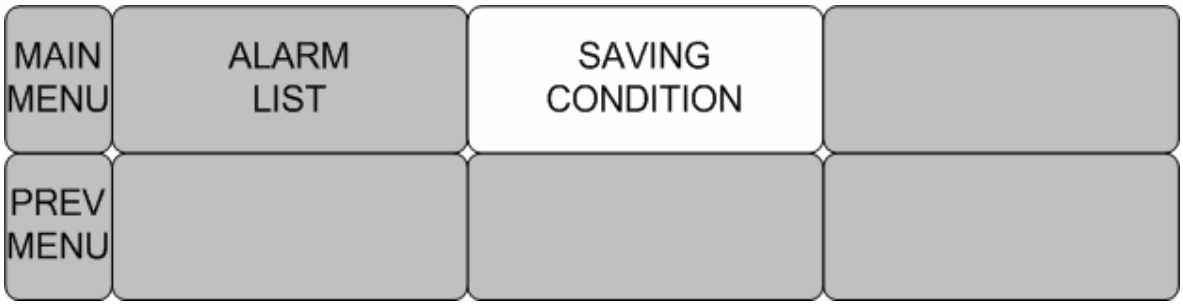
When an alarm activates, this shows the order of the alarms.

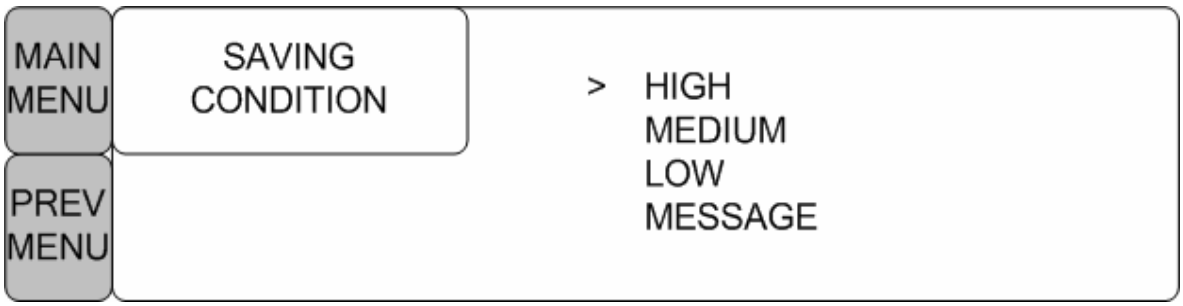




SAVING CONDITION

This determines the order in which triggered alarms are saved.





NURSE CALL

When an alarm is triggered, this activated the NURSE CALL function.

MAIN MENU	ALL ALARM LIMITS	ALARM PRINT: ON	ALARM VOLUME: OFF
PREV MENU	NURSE CALL: ON	ALARM LEVEL	ALARM REVIEW

MAIN MENU	ALL ALARM LIMITS	ALARM PRINT: ON	ALARM VOLUME: OFF
PREV MENU	NURSE CALL: OFF	ALARM LEVEL	ALARM REVIEW

3. SETUP

3.1 SETUP

DISPLAY

DEMO

USER SERVICE

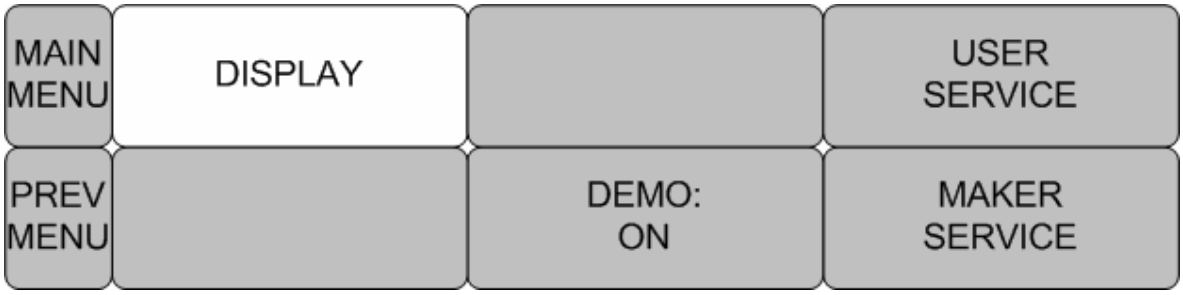
MAKER SERVICE

3.1 SETUP

DISPLAY : screen set menu

USER SERVICE : This is the menu to set the connection used to interface with an external computer

MAKER SERVICE : This is the basic adjustment menu used to adjust the features of this product.



DISPLAY

SET PARA：Measurement function selected.

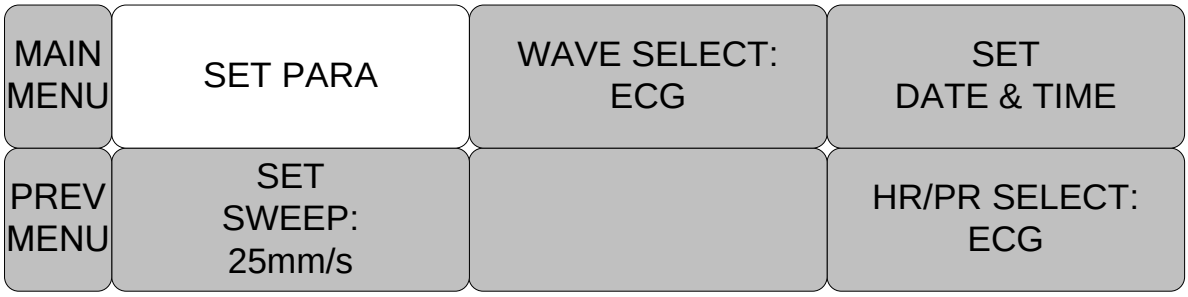
WAVE SELECT：Set wave pattern source at the bottom of the WINDOW with LARGE PARAMETER MODE.

SET DATE & TIME: Set and change date and time.

HR/PR SELECT：Set and select HR/PR source.

COLOR SELECT: Set screen display color.

SET SWEEP: Set speed of ECG, RESP WAVE DISPLAY



SET PARA

Select measurement function to use

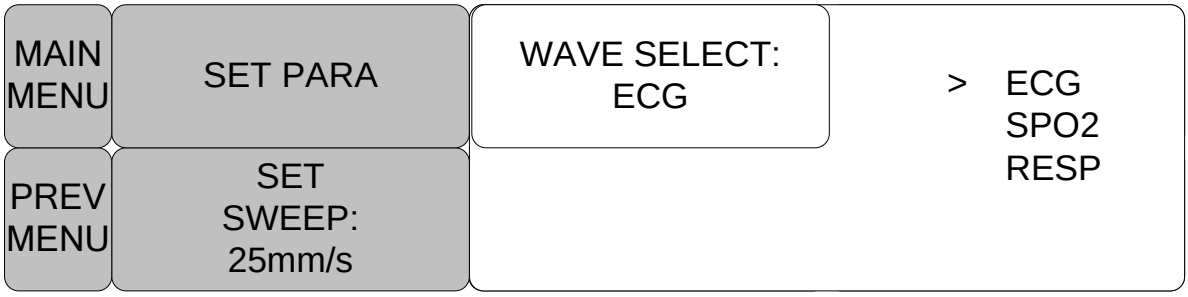
MAIN MENU	SET PARA	WAVE SELECT: ECG	SET DATE & TIME
PREV MENU	SET SWEEP: 25mm/s		HR/PR SELECT: ECG

PARAMETER WINDOW SET	
> RETURN	WINDOW ON/OFF
AUTO	ON
ECG	ON
SPO2	ON
RESP	OFF
NIBP	OFF
TEMP	ON

WAVE SELECT

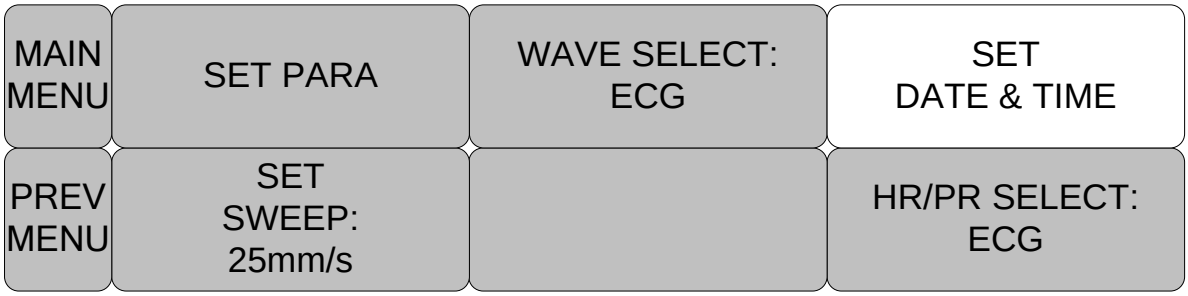
Select waveform to display in large parameter display.

MAIN MENU	SET PARA	WAVE SELECT: ECG	SET DATE & TIME
PREV MENU	SET SWEEP: 25mm/s		HR/PR SELECT: ECG



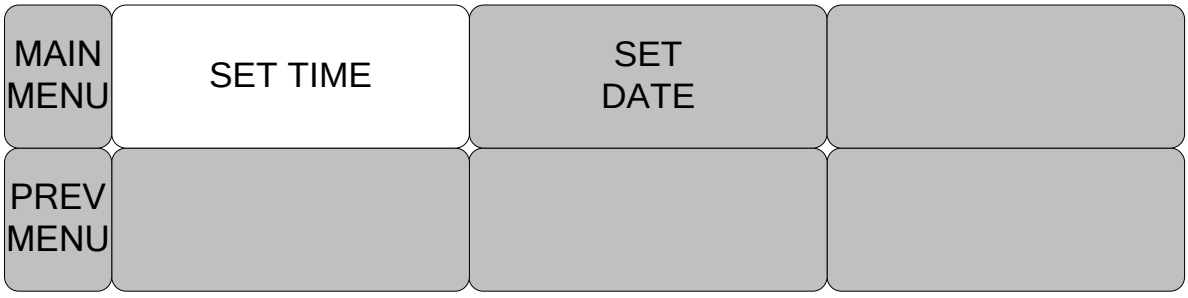
SET DATE & TIME

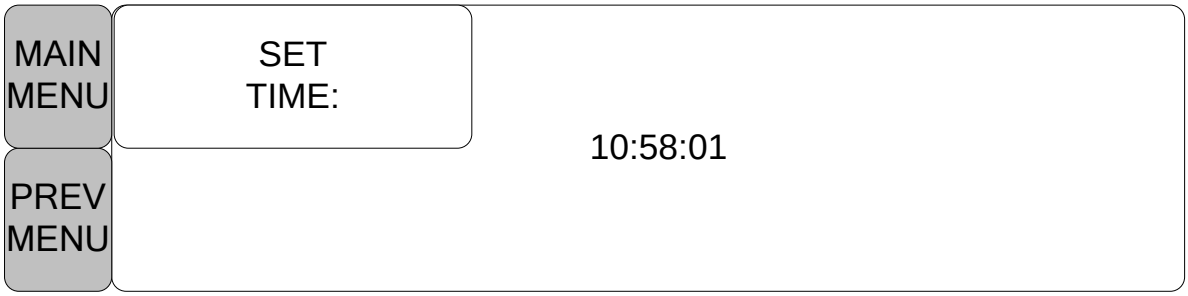
It has sub menu to set date and time.



SET TIME

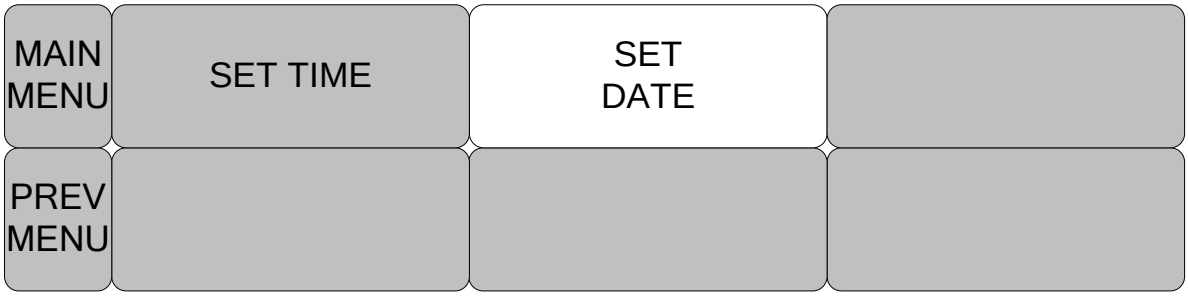
Set time of equipment.

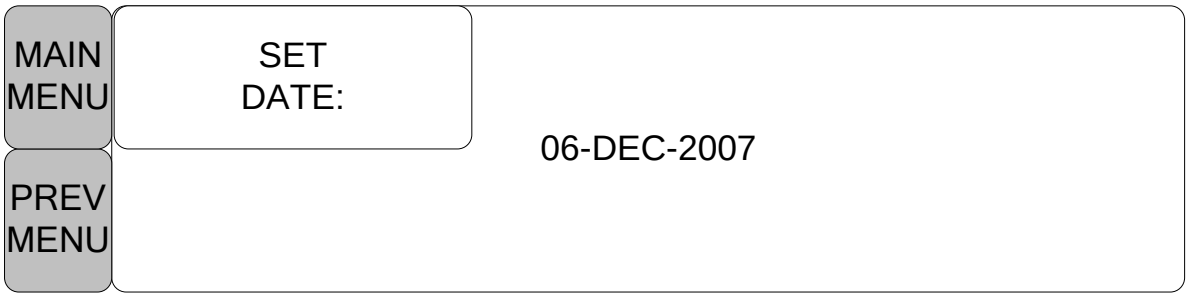




SET DATE

Set date of equipment

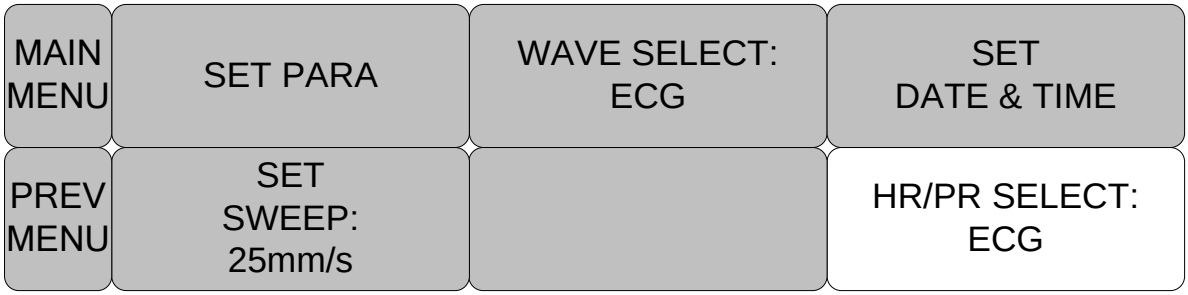


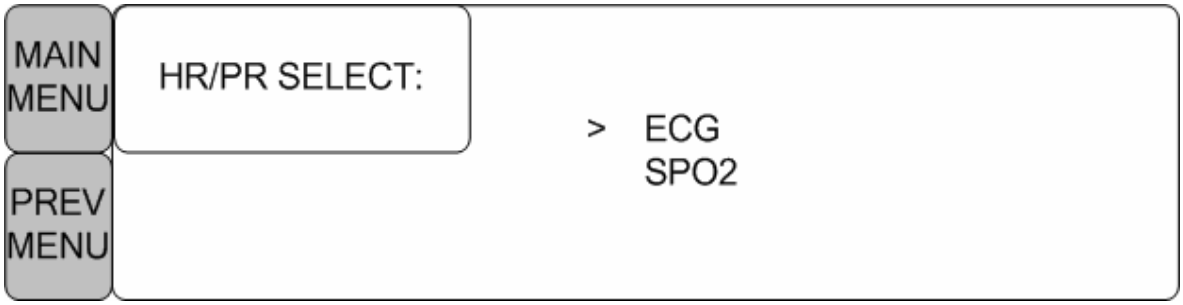


HR/PR SELECT

This menu is used to set the source that detects heart and pulse rate.

The source can select among ECG and SPO2.





SET SWEEP

Set speed of drawing wave signal pattern in this widow.

MAIN MENU	SET PARA	WAVE SELECT: ECG	SET DATE & TIME
PREV MENU	SET SWEEP: 25mm/s		HR/PR SELECT: ECG

MAIN MENU	SET SWEEP:	> 6.25 mm/s 12.5 mm/s 25 mm/s 50 mm/s	SET DATE & TIME
PREV MENU			HR/PR SELECT: ECG

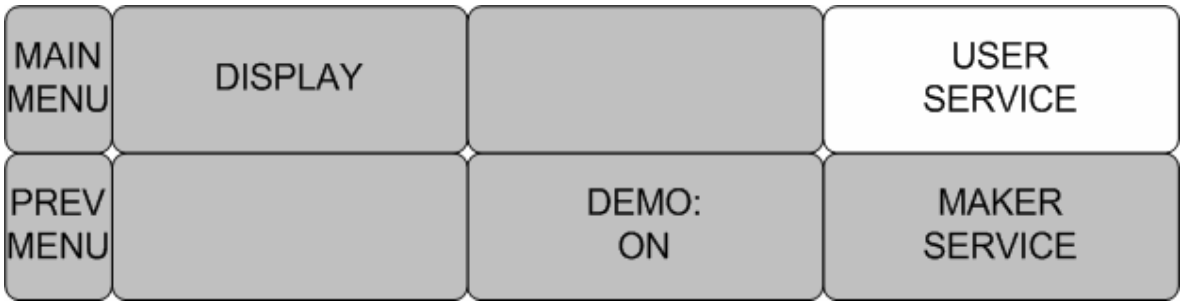
DEMO

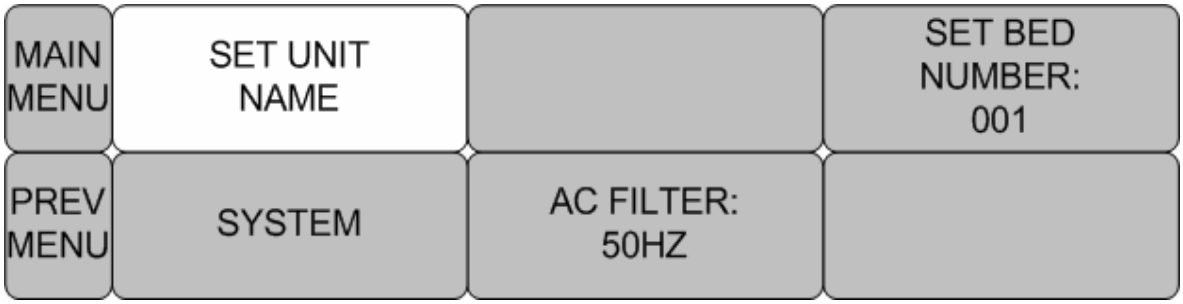
Set ON/OFF DEMONTRATION of equipment.

MAIN MENU	DISPLAY		USER SERVICE
PREV MENU		DEMO: ON	MAKER SERVICE

USER SERVICE

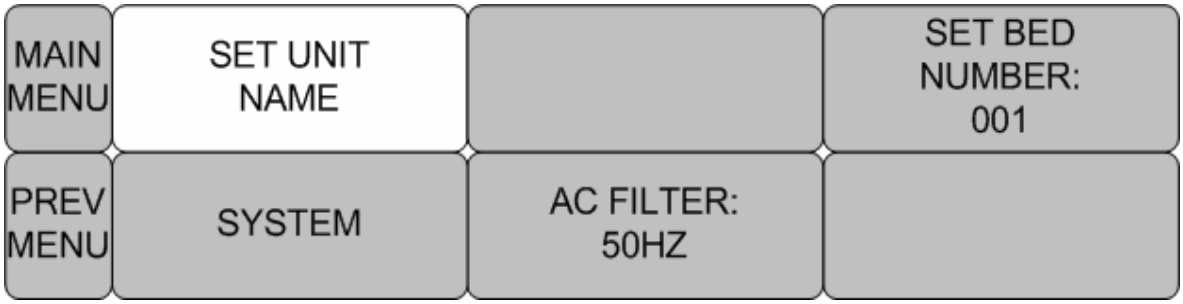
The user is able to set the communication parameters, power supply filter, and patient's age.

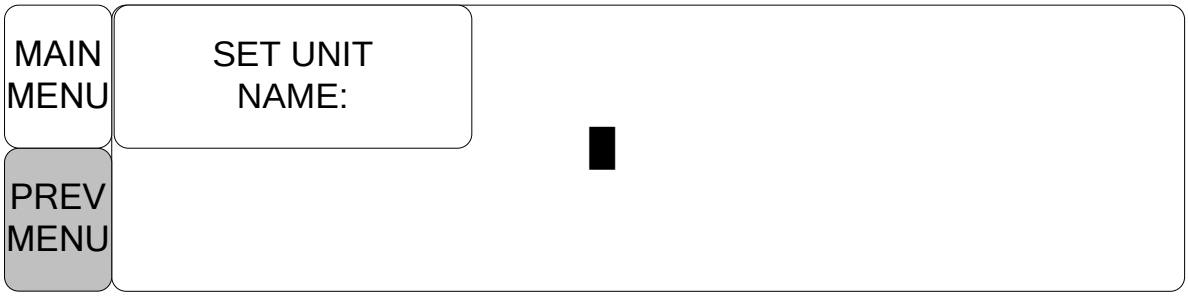




SET UNIT NAME

Set up for Equipment name.

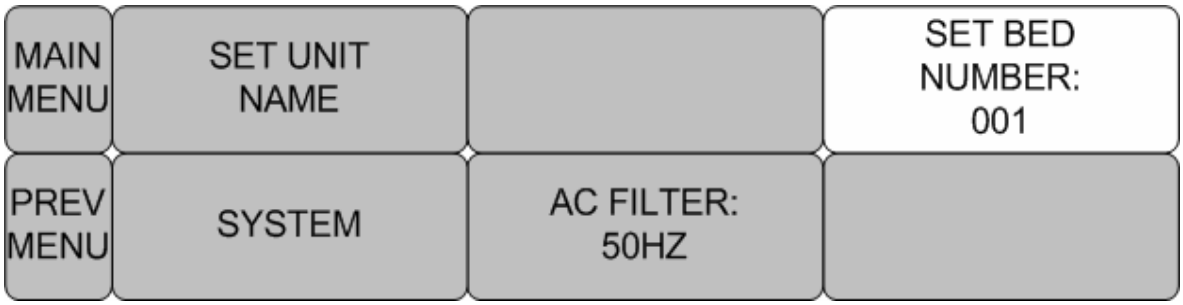


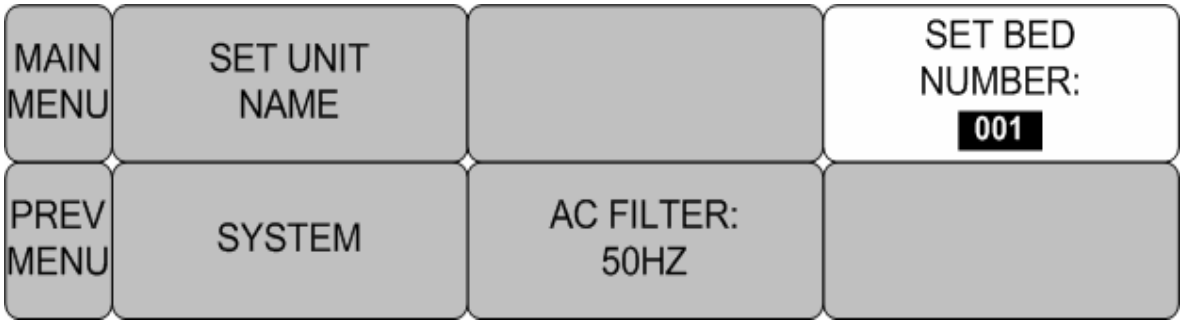


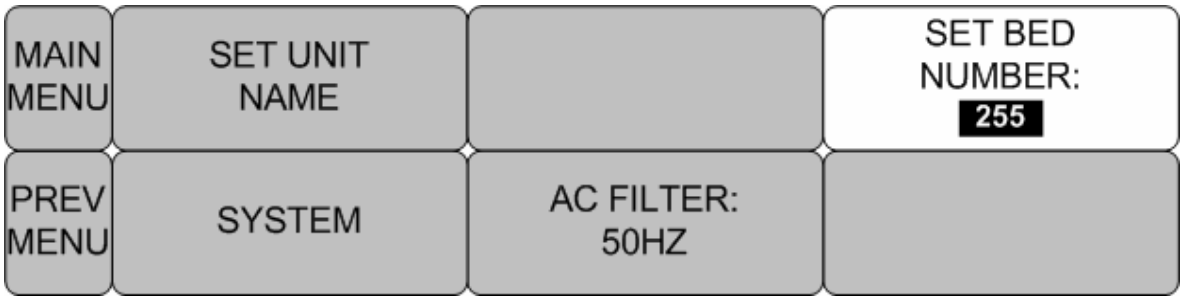
SET BED NUMBER

Set up for patient bed number.

Allowable setters are from 1 to 255.

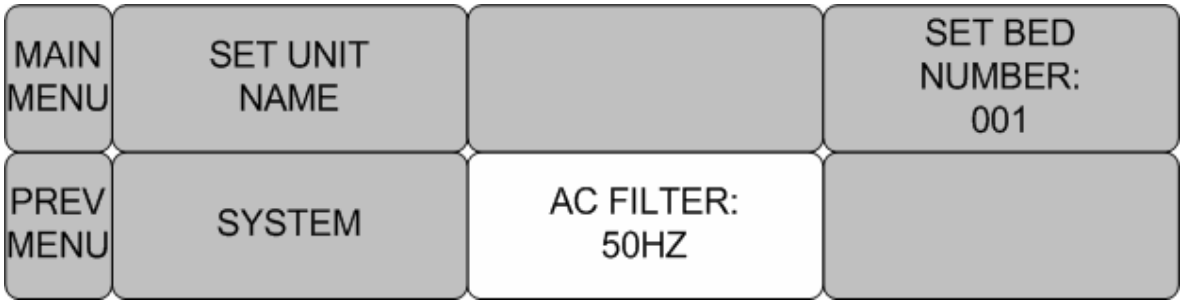


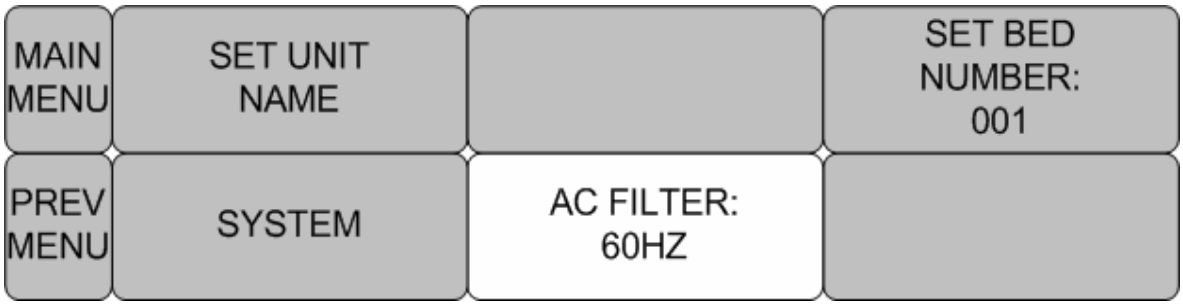




AC FILTER

AC FILTER is function where you can set power supply frequency. This feature is required because power supply frequency can be different from one country to another. . (The selectable frequencies are 50Hz and 60Hz.)





SYSTEM

System able to change and verify Equipment version information and system information

SYSTEM INFO SET	
RETURN	CONTENTS
MAIN VER	1.00BHCDDCX
CENTRAL	OFF
HOST IP	192.168. 30.100
DEVICE IP	192.168. 30.101
SUBNET	255. 255. 255. 0
GATEWAY	192.168. 30. 1
MAC ADD	00: 02: BD: 80: 00: 00
DISPLAY	LCD

MAKER SERVICE

Maker service is a menu is used by manufacturers.

4. TREND

4.1 TREND

GRAPHIC TREND

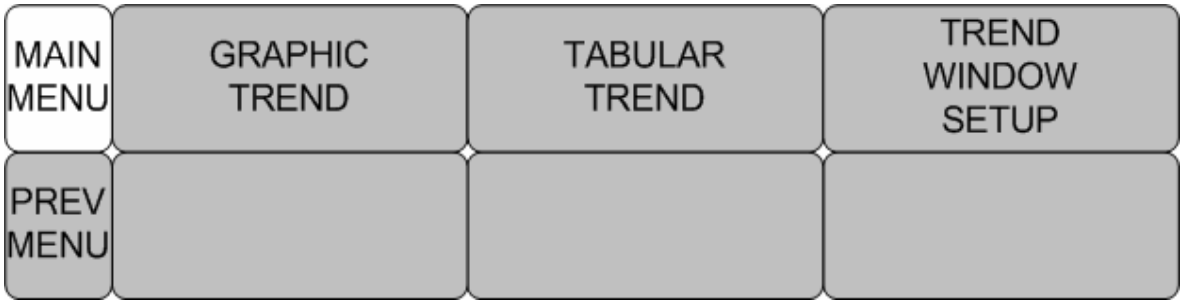
TABLE TREND

TREND WINDOW SETUP

4.1 TREND

TREND shows saved data graphically displayed with numeric values.

Real-time data recording duration is 1 minute. Amount of saving time is for this data will be saving for 128hours.



: Move to main screen

: Move within the tables

: Move up to other analysis function

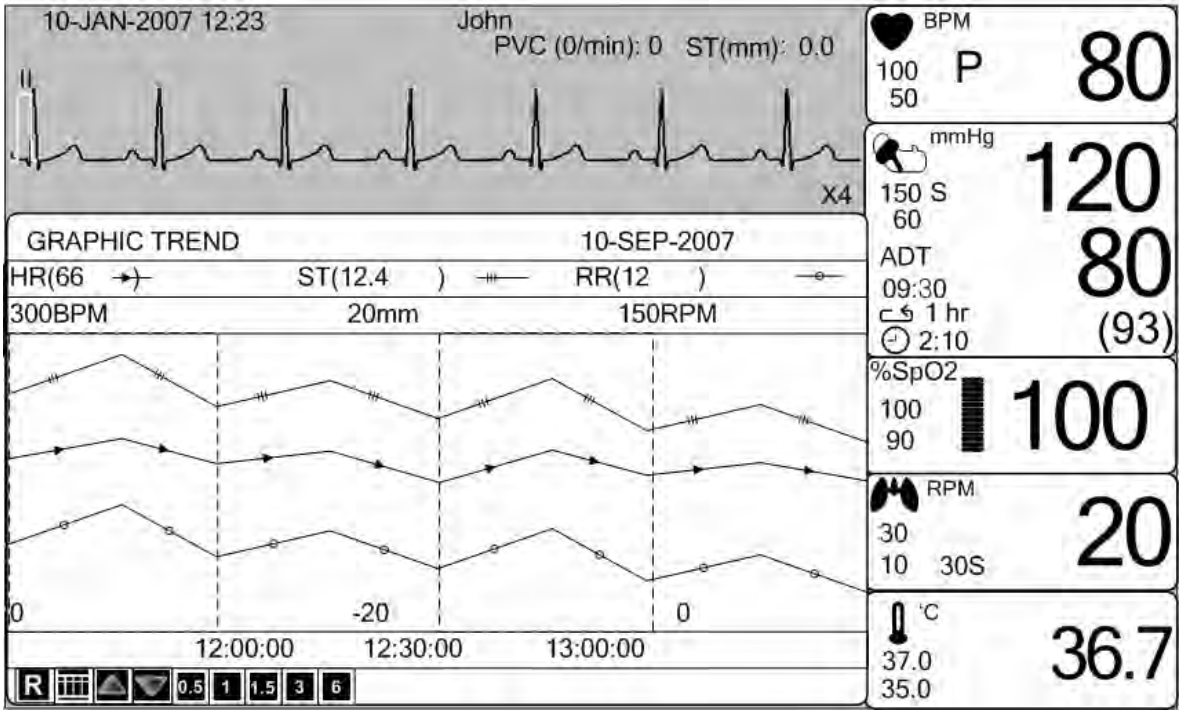
: Move down to other analysis function

: Time period set menu

GRAPHIC TREND

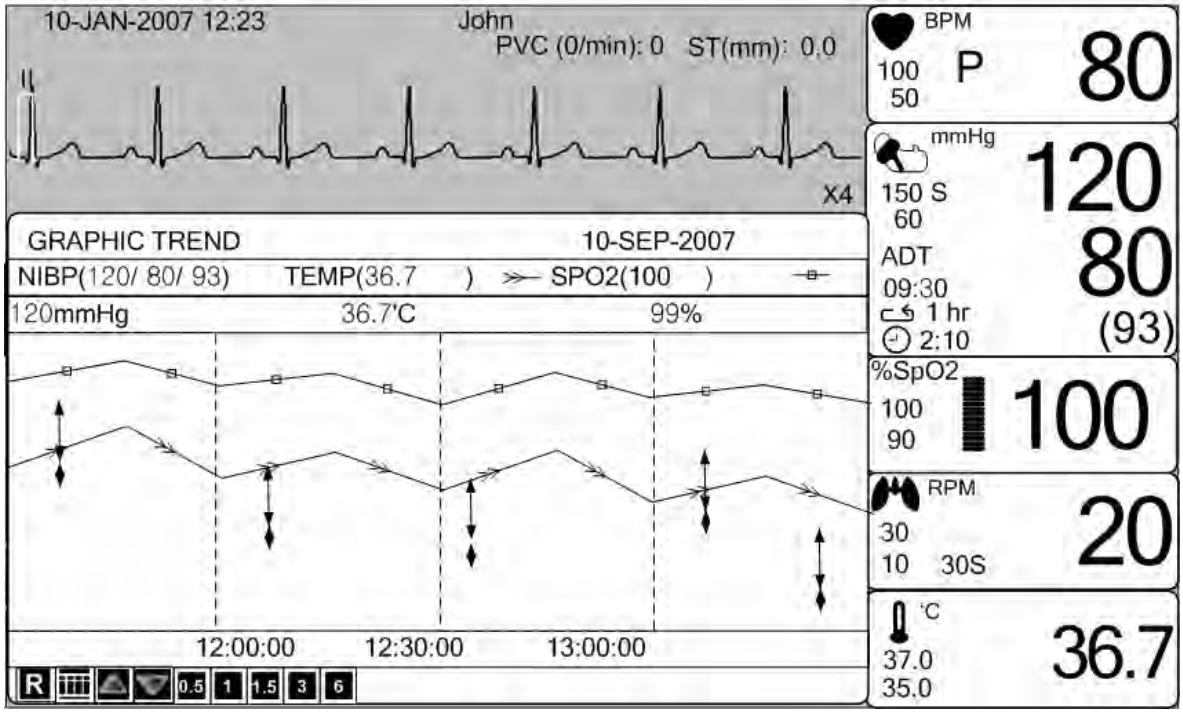
Wave Data can be stored and seen according to section.

MAIN MENU	GRAPHIC TREND	TABULAR TREND	TREND WINDOW SETUP
PREV MENU			



TIME PERIOD

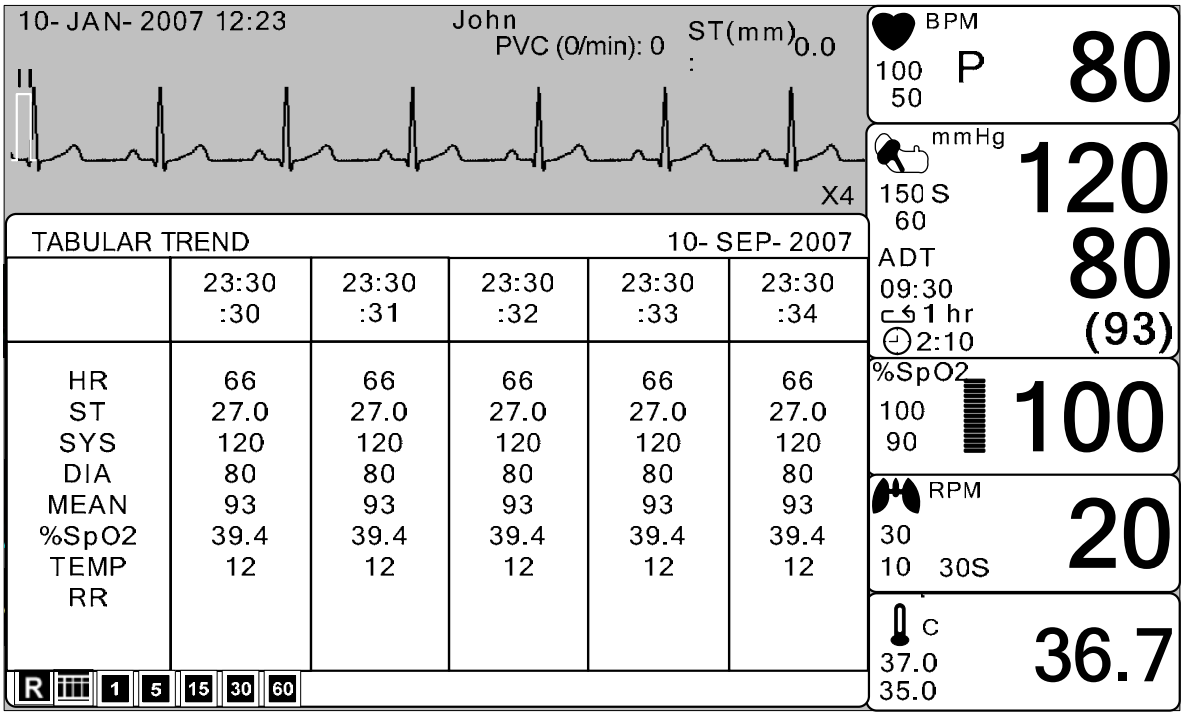
One can set up and store data and time that one can see in a screen.



TABULAR TREND

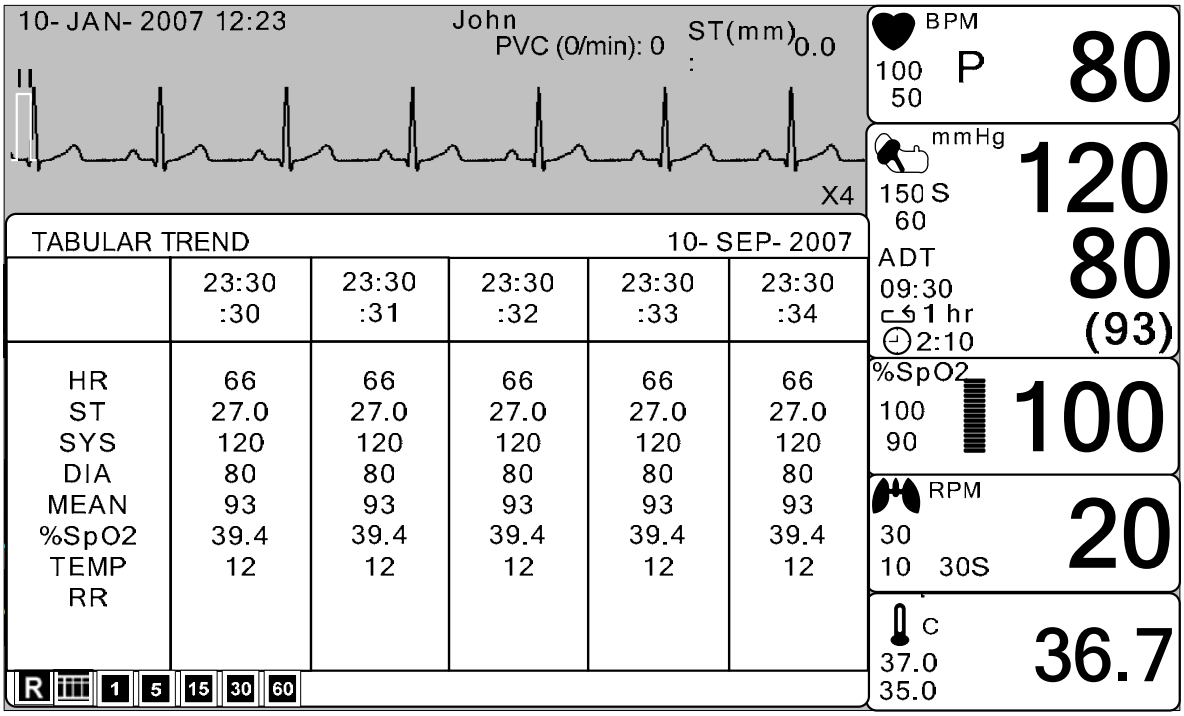
One can see the stored data at the time previously set up.

MAIN MENU	GRAPHIC TREND	TABULAR TREND	TREND WINDOW SETUP
PREV MENU			



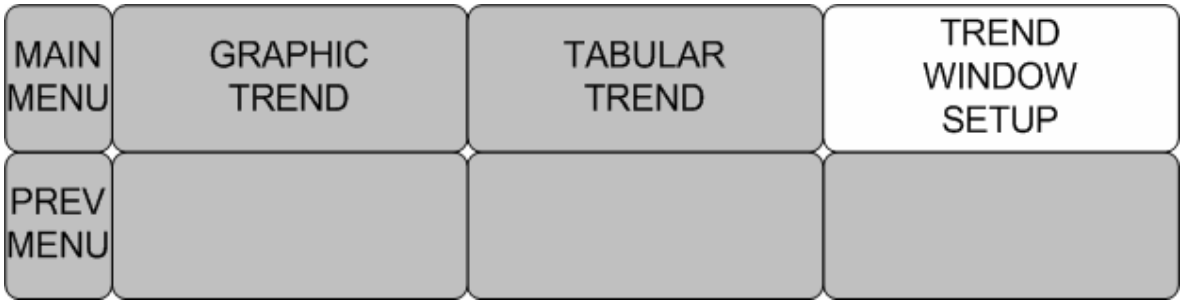
TIME INTERVAL

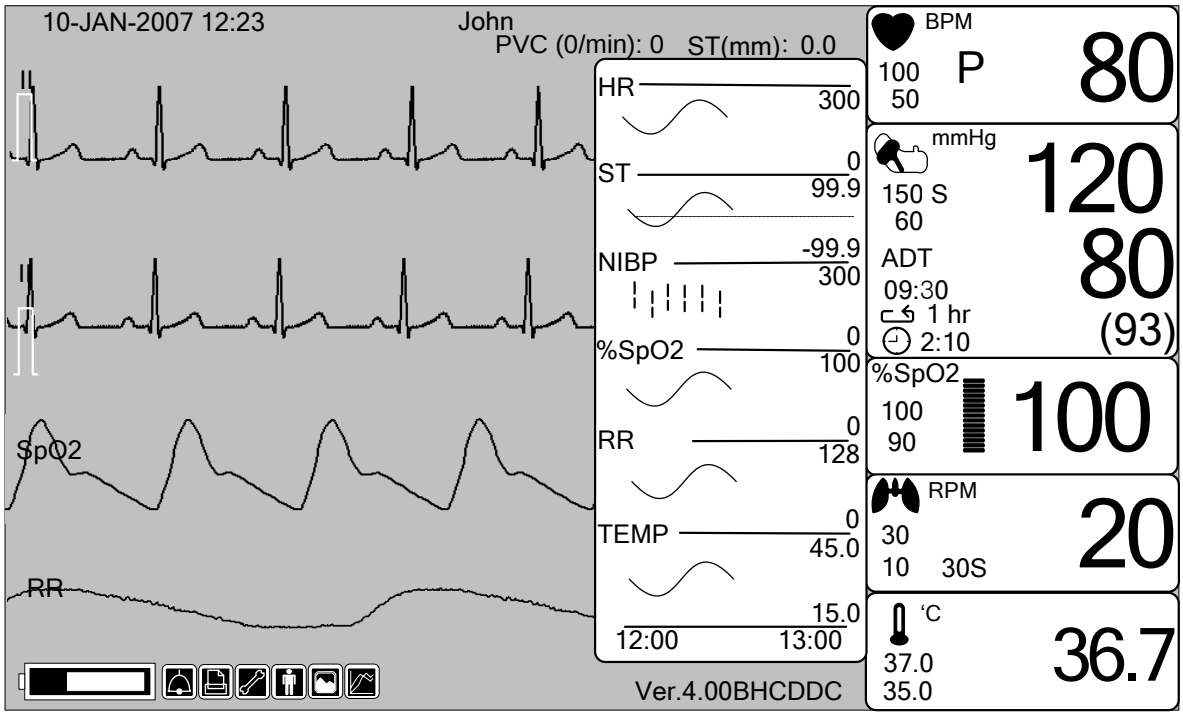
One can store data and set up time.



TREND WINDOW SETUP

Set the trend display window that will show the real time wave window.





TIME PERIOD

Set visible time period in a screen.

MAIN MENU	TIME PERIOD: 30MINS	SET TREND PARA	
PREV MENU			

MAIN MENU	TIME PERIOD:	> 30MINS 60MINS 90MINS 3HRS 6HRS 12HRS
PREV MENU		

SET TREND PARA

Set parameter for display in a screen.

MAIN MENU	TIME PERIOD: 30MINS	SET TREND PARA	
PREV MENU			

SET TREND PARA			
RETURN	ON/OFF		
HR	ON		
ST	ON		
%SPO2	ON		
PR	OFF		
RR	OFF		
NIBP	OFF		
TEMP	OFF		

TREND PRINT

Graphic: select the number which selects a graphic trend and press print to prints the selected trend.

Table: select the table number to be print and press print to receive print all the data in the selected patient admit (Admit) table.

5. ECG

5.1 Outline

Color and Name for Each Cable Size

ECG Connector Location and Measurement Cable

5 Lead Electrode Attached Location

3 Lead Electrode Attached Location

Method to Attach Electrode to Baby

5.2 ECG Data Window

5.3 ECG Data Setup

TRACE 1 LEAD SELECT

ALARM LIMIT

ALARM

QRS VOLUME

ECG SIZE

HEART RATE SOURCE

ECG SPEED

ANALYSIS SETTING

5.1 Introduction

It calculates the heart rate with 3 or 5 leads ECG signal acquisition and perform the alarm according to the setting value.

Colors and Standards of Cables

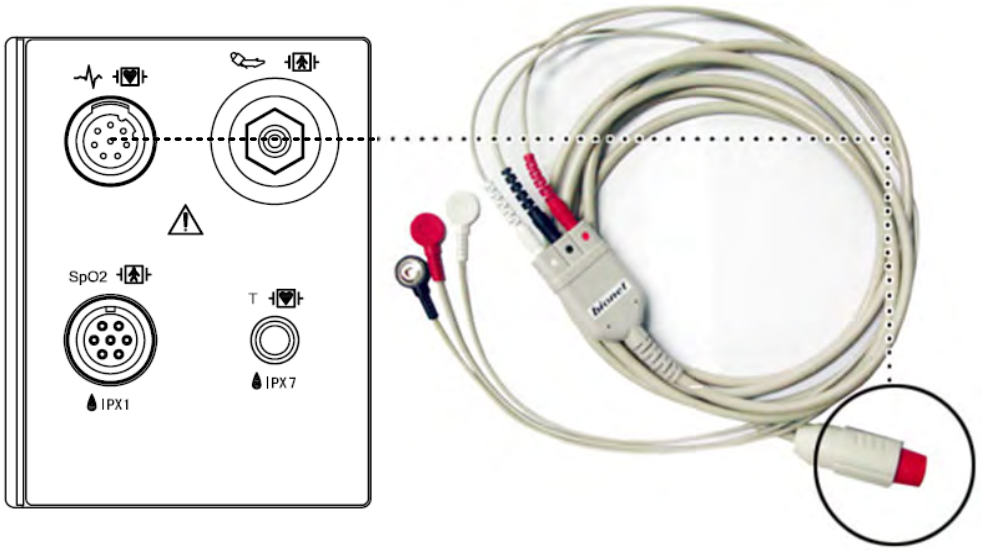
Leadwire	AHA Color code	AHA Label	IEC Color code	IEC Label
Right arm	White	RA	Red	R
Left arm	Black	LA	Yellow	L
Right leg	Green	RL	Black	N
Left leg	Red	LL	Green	F
V1(precordial)	Brown	V1	White	C1

AHA：American Heart Association (U.S.A. standard)

IEC：International Electro technical Commission (Europe standard)

Position of ECG Connector and Measuring Cable

ECG connecter +detect cable



Attaching Electrodes to the Patient

1. Shave exess hair. With a piece of cotton pad moistened with alcohol, clean the patient's skin where the electrodes should be mounted. Avoid wrinkled or uneven skin areas. Wipe off the alcohol with a dry cotton pad.

2. Open the electrode package and take out the electrode.

3. Remove the backing paper from the electrode. Be careful not to touch the adhesive side.

4. Attach the disposable electrode to the previously cleaned skin. Avoid wrinkled and uneven skin areas.

5. The electrode lead which is connected to the monitor onto the electrode.

6. Fasten the electrode lead to the skin with surgical tape with an extra length of wire between the tape and the electrode. This prevents body movement from moving the electrode lead.

Note
✓ To maintain good contact between the electrode and skin, check that the paste of the disposable electrode is not dry. ✓ When contact of the disposable electrode becomes poor, replace the electrode with a new one immediately. Otherwise, contact impedance between the skin and electrode increase and the correct ECG cannot be obtained. ✓ If the contact is bed before the expiration date on the package, replace the electrode with a new one. ✓ To obtain a stable ECG waveform rub the skin with "skin Pure" skin preparation gel or tincture of Benzion. ✓ Shall use only the CE certified disposable electrode.

Choosing an ECG lead for Arrhythmia Monitoring

It is very important to select a suitable lead for arrhythmia monitoring.

Guidelines for non-paced patients:

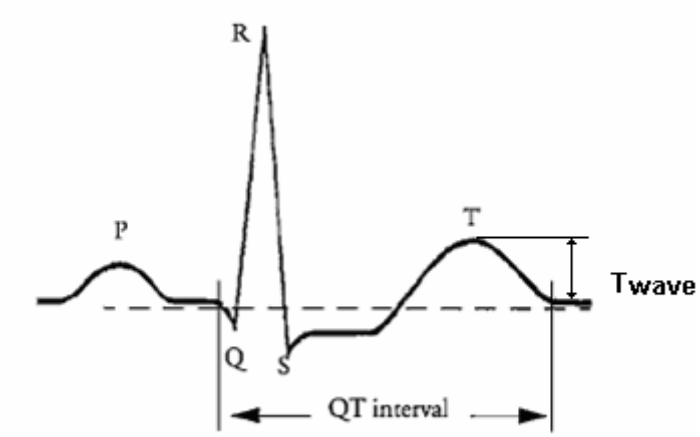
- ✓ QRS should be tall and narrow(recommended amplitude > 0.5mV)
- ✓ R wave should be above or below the baseline (but not bi-phasic)
- ✓ T wave should be smaller than 1/3 R-wave height.
- ✓ The P-wave should be smaller than 1/5 R-wave height.

For paced patients, in addition to the above,:

- ✓ Not wider than the normal QRS
- ✓ The QRS complexes should be at least twice the height of pace pulses.
- ✓ Large enough to be detected, with no re-polarization.

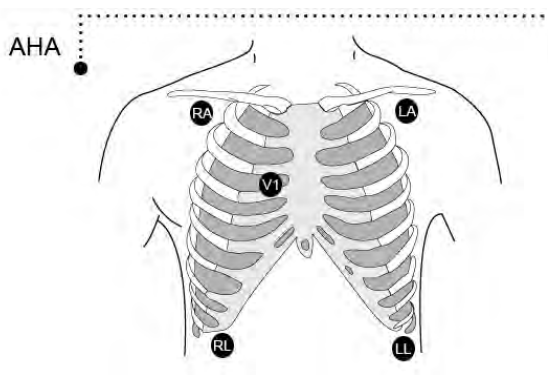
To prevent detection of P-waves or baseline noises as QRS complexes, the minimum detection level for QRS complexes is set at 0.15mV. Adjusting the ECG wave size on the monitor display(gain adjustment)does not affect the ECG signal which is used for arrhythmia analysis. If the ECG signal is too small, you may get false alarms for asystole.

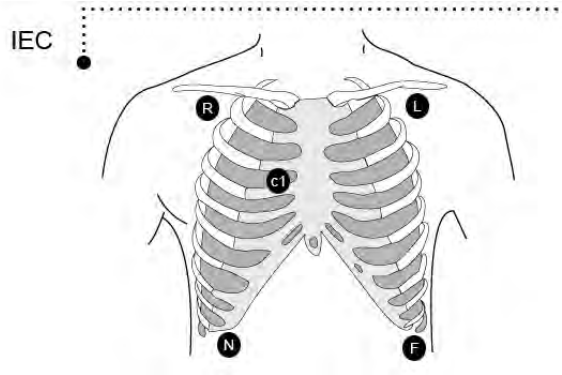
Information on the ECG waveform



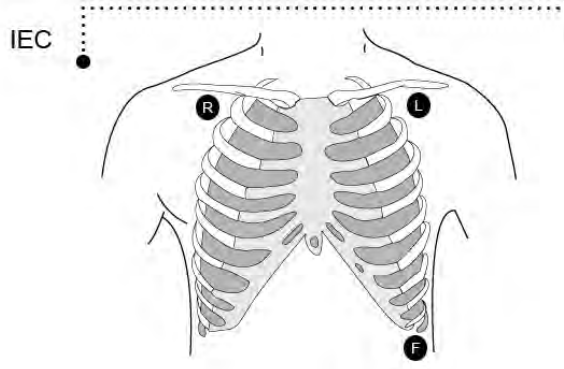
When ECG signal is 80bpm T-wave duration is 180ms, and the QT interval is 350ms.

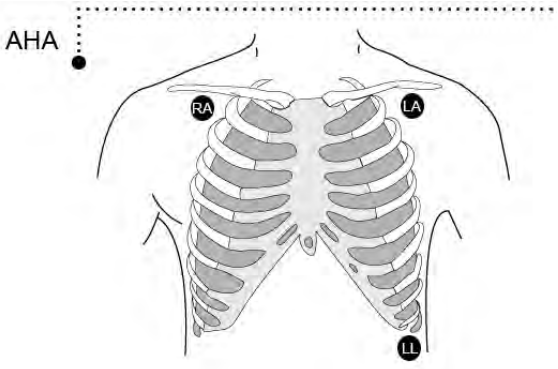
5 Position of 5-Lead



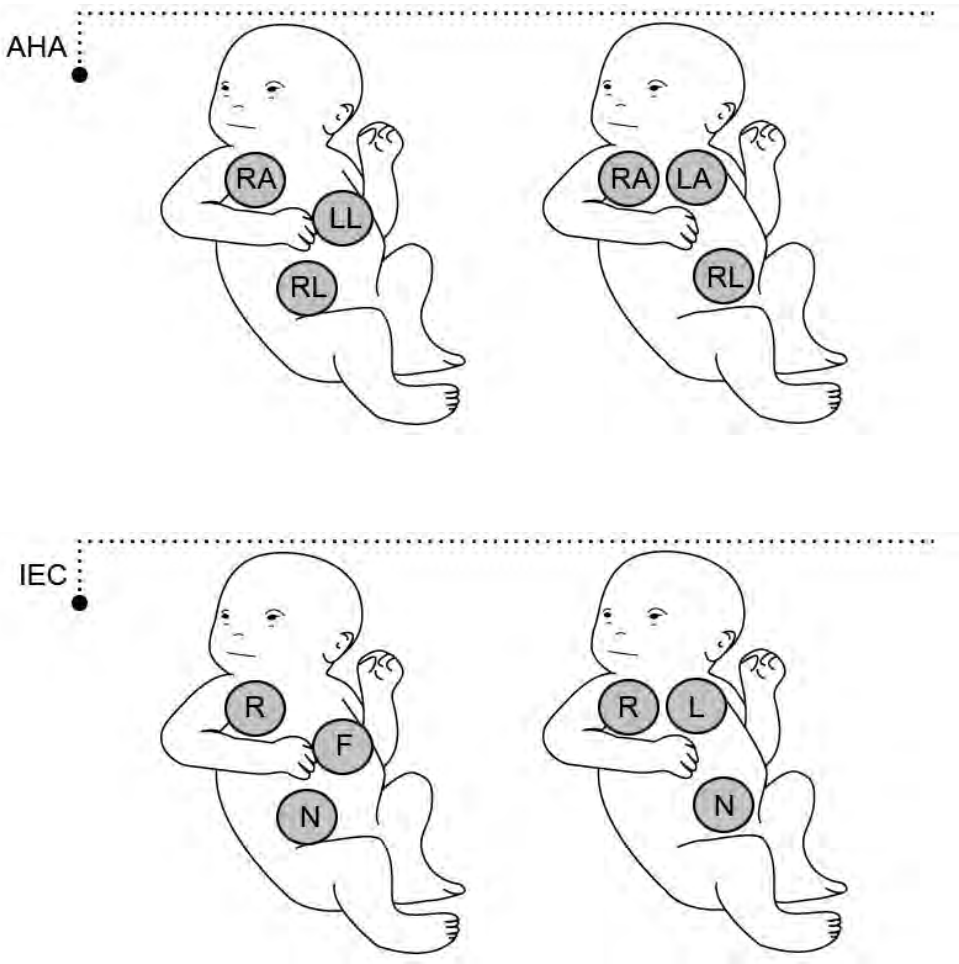


Position of 3-Lead Wrier Electrode

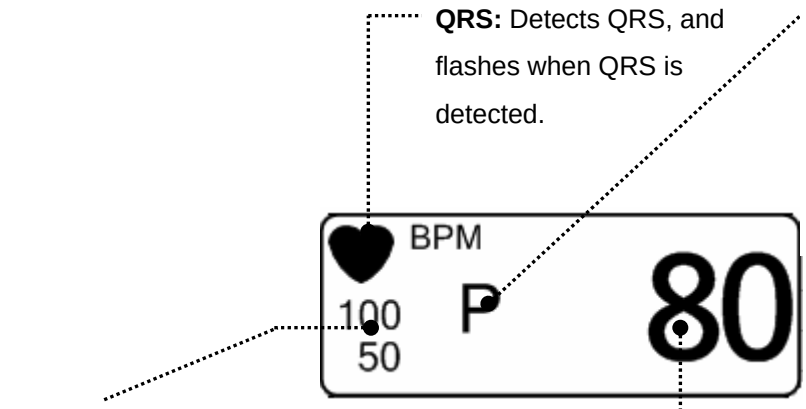




How to Attach the NEONATE Electrode



5.2 ECG Data Window



QRS: Detects QRS, and flashes when QRS is detected.

Pace Detector Indicators: Detects and displays the patient's pace maker and flashes.

Heart Rate Alarm Limit: Decides the QRS limits, and gives an alarm if a value is over the limits.

Heart Rate: Displays heart rate per minute.

Note
ECG Wave Display is always on when the cable is connected.

The heart rate is calculated by a moving average. The monitor detects 8 consecutive beats, averages the R-R intervals of the latest 8 beats and uses this average to calculate the current heart rate. When a new beat is detected, the heart rate is recalculated using the latest 8beats. The heart rate display is updated every 3 seconds.

Heart rate meter updates a new heart rate for a step increase or decrease in 10 seconds maximum. When ventricular tachycardia is detected, the alarm set in 5 seconds maximum.

Check that the delay time of the output signal (alarm trigger 80ms maximum) is within the range of the connected equipment.

Safety Precautions

Warning
CABLES — Route all cables away from patient's throat to avoid possible strangulation. **CONDUCTIVE CONNECTIONS** — Extreme care must be exercised when applying medical electrical equipment. Many parts of the human/machine circuit are conductive, such as the patient, connectors, electrodes, transducers. It is very important that these conductive parts do not come into contact with other grounded, conductive parts when connected to the isolated patient input of the device. Such contact would bridge the patient's isolation and cancel the protection provided by the isolated input. In particular, there must be no contact of the neutral electrode and ground. **DEFIBRILLATION** — Do not come into contact with patients during defibrillation. Otherwise serious injury or death could result. To avoid the risk of serious electrical burn, shock, or other injury during defibrillation, all persons must keep clear of the bed and must not touch the patient or any equipment connected to the patient. After defibrillation, the screen display recovers within 10seconds if the correct electrodes are used and applied in accordance with the manufacturer's instructions. ECG cables can be damaged when connected to a patient during defibrillation. Check cables for functionality before using them again. The peak of the synchronized defibrillator discharge should be delivered within 60ms of the peak of the R wave. The signal at the ECG output on the patient monitors is delayed by a maximum of 30ms. If the ECG waveform on the screen is too unstable to synchronize with the patient's heart beat because of the following reason, remove the cause of an alarm, message, or unstable ECG, and then use a stable ECG lead for synchronization. ✓ ECG electrode is detached or broken. Lead wire is detached or broken. ✓ Lead wire moves. AC interference, EMG noise or noise from ESU is superimposed. ✓ Connection cable is broken or has a short circuit. Connector has poor contact.

INTERFACING OTHER EQUIPMENT — Devices may only be interconnected with each other or to parts of the system when it has been determined by qualified biomedical engineering personnel that there is no danger to the patient, the operator, or the environment as a result. In those instances where there is any element of doubt concerning the safety of connected devices, the user must contact the manufacturers concerned (or other informed experts) for proper use. In all cases, safe and proper operation should be verified with the applicable Manufacturer's instructions for use, and system standards IEC 60601-1-1/EN 60601-1-1 must be complied with.

Electrosurgery Unit

- ✓ Electrosurgical units(ESU) emit a lot of RF interference. If the monitor is used with an ESU,RF interference may affect the monitor operation.
- ✓ Locate the monitor as far as possible from the ESU. Locate them on opssite sides of the operating table, if possible.
- ✓ Connect the monitor and ESU to different AC outlets located as far as possible from each other.
- ✓ When using this monitor with an electrosurgical unit, its return plate and the electrodes for monitoring must be firmly attached to the patient. If the return plate is not attached correctly,it may burn the patient's skin where the electrodes are attached.

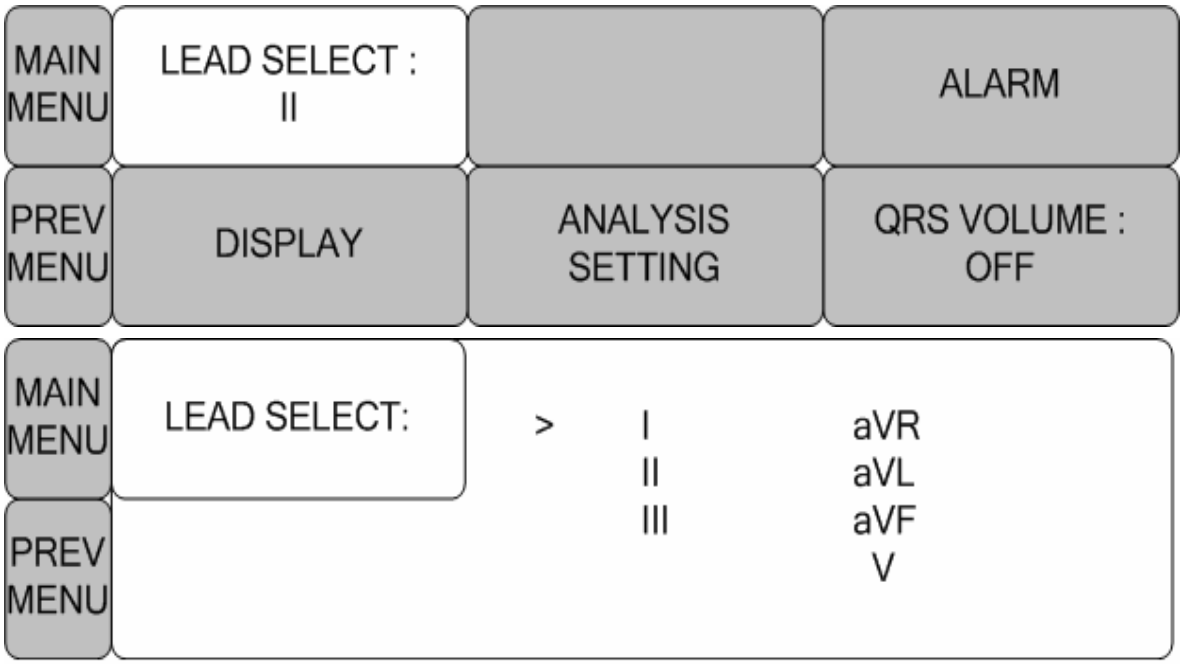
5.3 ECG Data Setup

A setup window appears at lower part of the screen when the Trim Knob Key is pressed in the ECG Parameter Window.

Selection is made by pressing the Trim Knob Key, while movement across the menu is performed by turning the key either clock or anticlockwise.

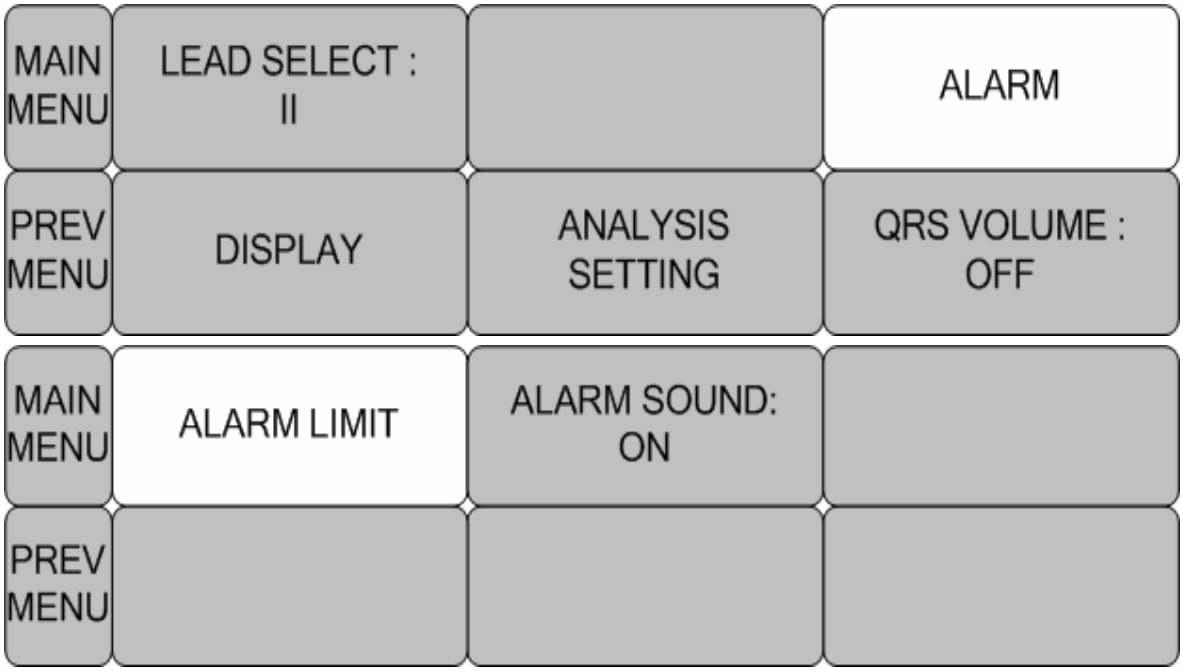
TRACE 1 LEAD SELECT

Select channels from I to V in ECG



ALARM LIMIT

Alarm Limit is 0 ~ 300.

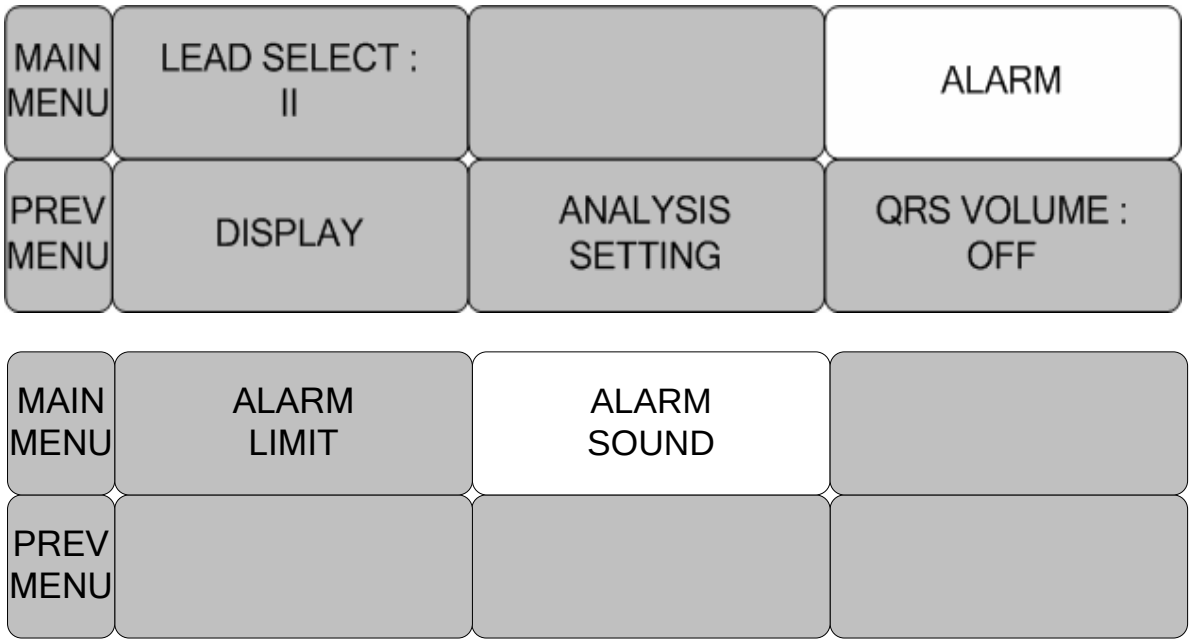


ECG ALARM LIMIT

RETURN	UNITS	LOW	HIGH
HR	bpm	60	120

ALARM SOUND

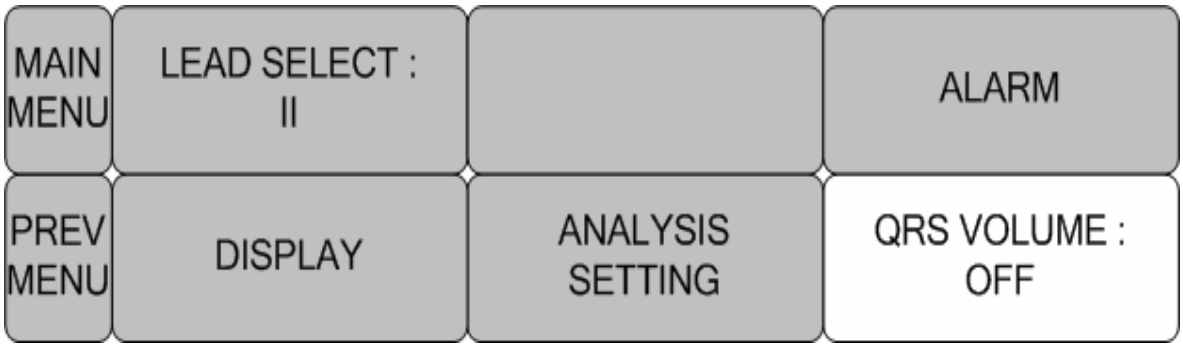
Set ON/OFF of ECG alarm sound.

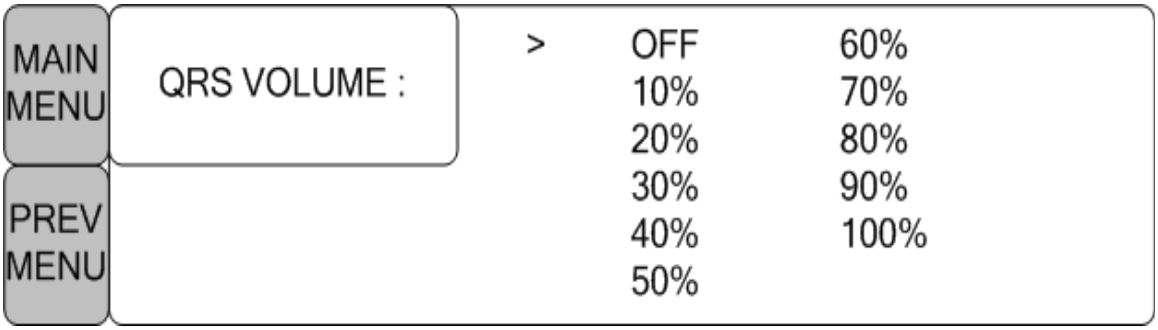


ECG ALARM SOUND	
> RETURN	ECG ALARM SOUND
HR	ON
ARRHYTHMIA	ON
ST	ON
PVC	OFF

QRS VOLUME

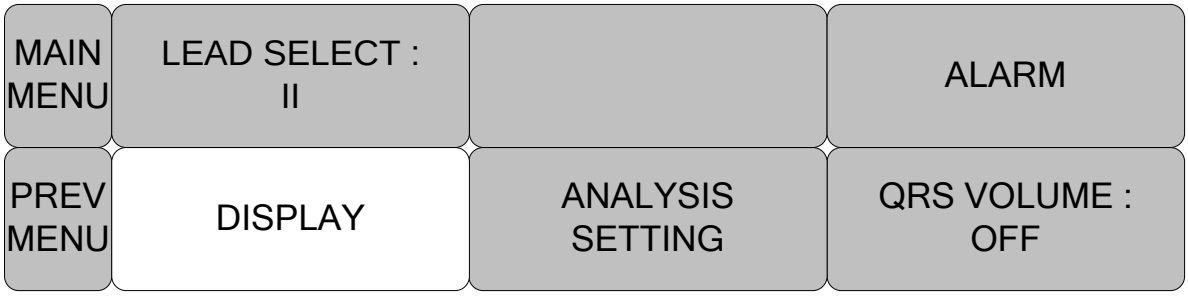
Move the Key to select a volume rate from OFF, 10% to 100%.





DISPLAY

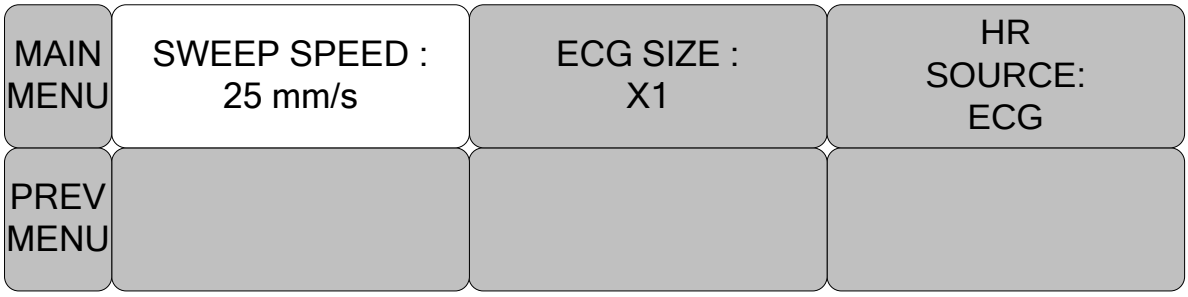
Set the sweep speed and waveform size.

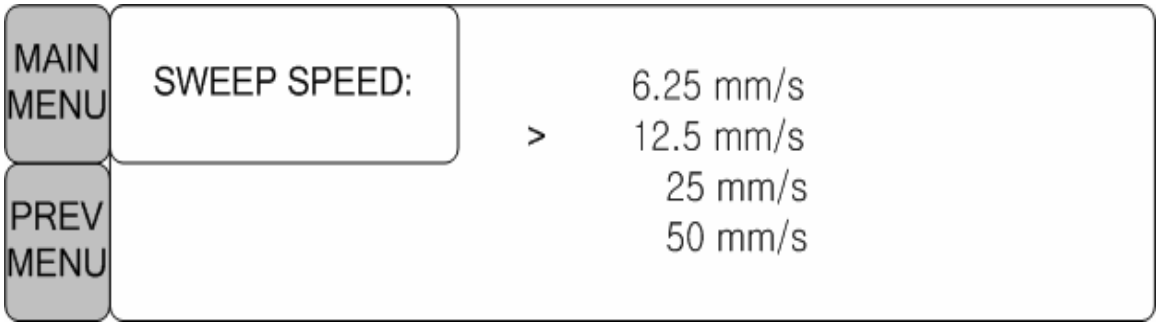


ECG SPEED

ECG speed is 25 mm/s.

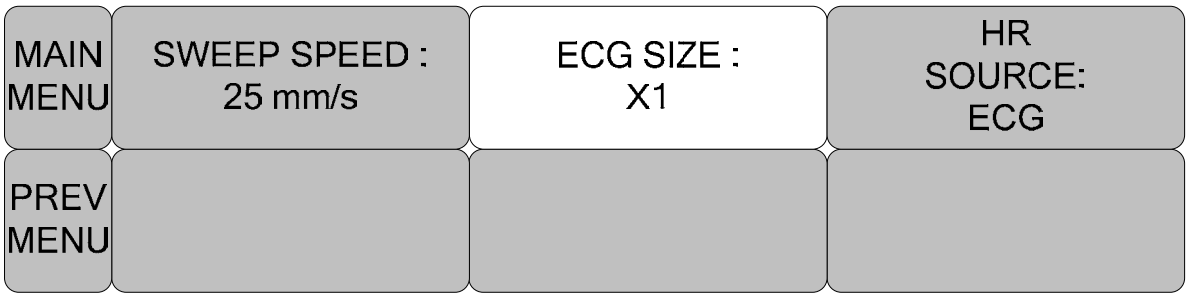
Speed is changeable to 6.25, 12.5, 25, 50mm/s.

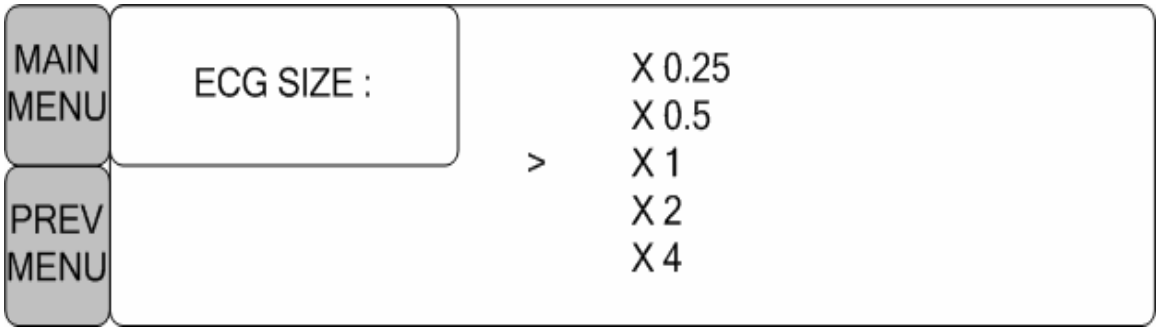




ECG SIZE

The size is changeable to X0.5, X1, X2, X4.





HR SOURCE

MAIN MENU	SWEEP SPEED : 25 mm/s	ECG SIZE : X1	HR SOURCE: ECG
PREV MENU			

MAIN MENU	SWEEP SPEED : 25 mm/s	HEART RATE SOURCE:	> ECG SPO2 AUTO
PREV MENU			

ANALYSIS SETTING

Analysis setting divided to 3 menus.

ECG FILTER：One may select from three frequency types for WAVE FILTER.

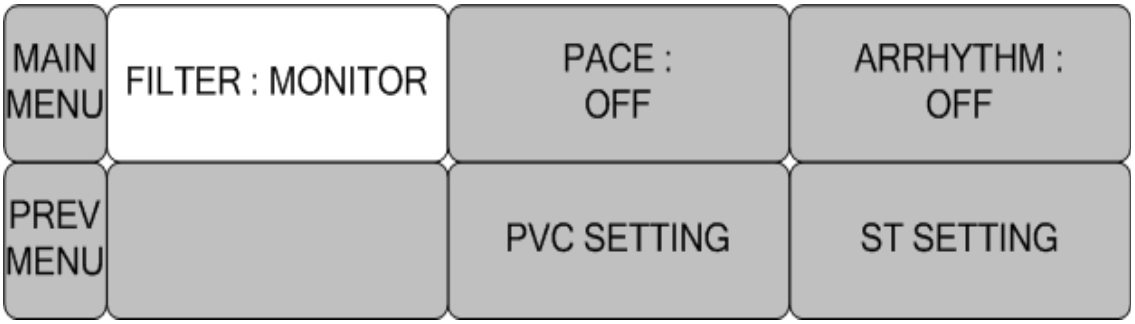
MONITOR 0.5Hz ~ 40Hz

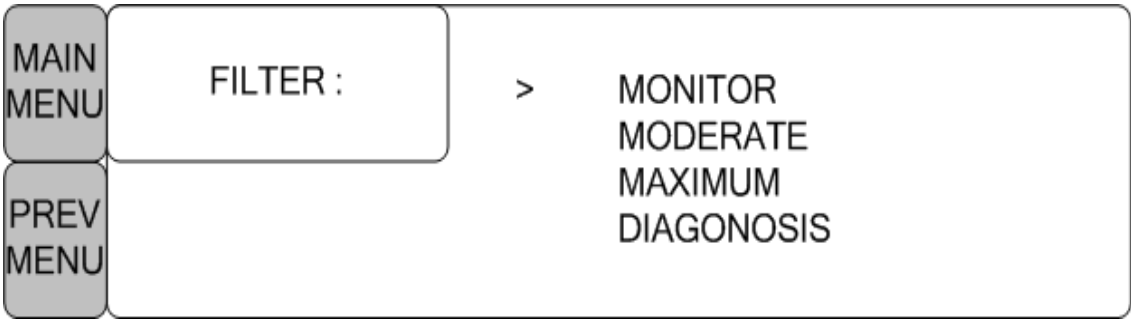
MODERATE 0.5Hz ~ 25Hz

MAXIMUM 5Hz ~ 25Hz

DIAGONOSIS is

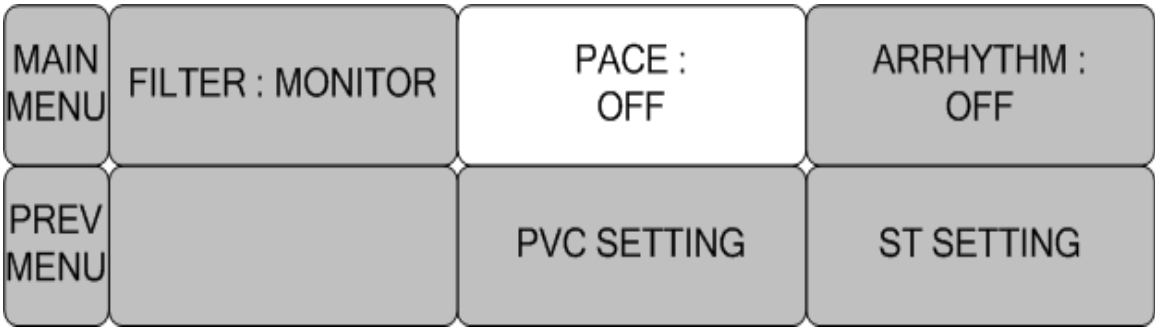
MAIN MENU	LEAD SELECT : II		ALARM
PREV MENU	DISPLAY	ANALYSIS SETTING	QRS VOLUME : OFF





PACE：Sets up ON/OFF to indicate that the patient has PACE.

The PACE menu option enables/disables the pacemaker detection program.



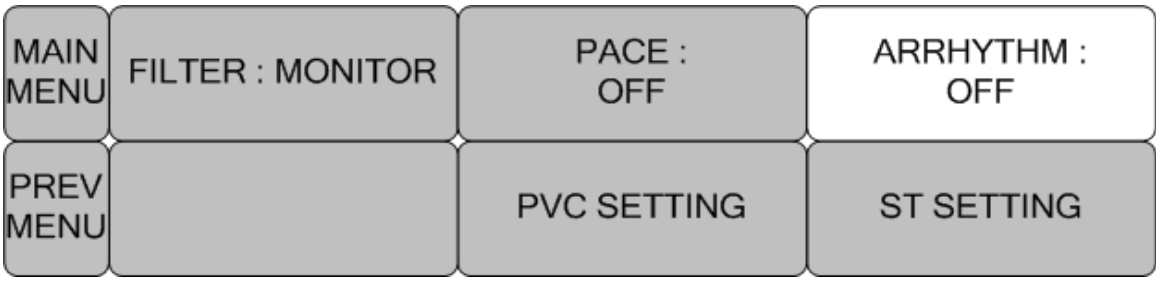
Be aware of the following when monitoring a patient with a pacemaker.

Warning
FALSE CALLS—False low heart rate indicators or false asystole calls may result with certain pacemakers because of electrical overshoots. MONITORING PACEMAKER PATIENTS—Monitoring of pacemaker patients can only occur

with the pace program activated.
PACEMAKER SPIKE—An artificial pacemaker spike is displayed in place of the actual pacemaker spike. All pacemaker spikes appear uniform. Do not diagnostically interpret pacemaker spike size and shape.
PATIENT HAZARD—A pacemaker pulse can be counted as a QRS during asystole in either pace mode. Keep pacemaker patients under close observation.

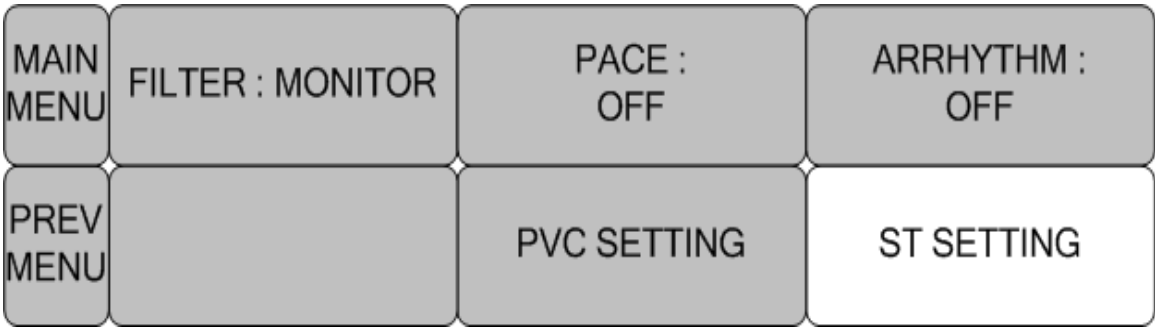
PACEMAKER PATIENTS. Rate meters may continue to count the pacemaker rate during occurrences of cardiac arrest or some arrhythmias. Do not rely entirely upon rate meter ALARMS. Keep pacemaker patients under close surveillance.

ARRHYTH：Sets up ON/OFF to indicate detection of diagnosis (ASYS, VTAC/VFIB, VTAC). The Analysis algorithm simultaneously uses leads I, II, III, and the V lead for ECG and arrhythmia analysis.



ASYSTOLE: Ventricular asystole occurs whenever the displayed heart rate drops to zero.
VTAC/VFIB: Ventricular fibrillation occurs when the ECG waveform indicates a chaotic ventricular rhythm With an average heart rate greater than or equal to 200beats per minute.
VTAC: Ventricular tachycardia occurs when a run of six or more ventricular beats is detected With an average heart rate greater than or equal to 150beats per minute.

ST SETTING : ST signal and setting related ST menu.

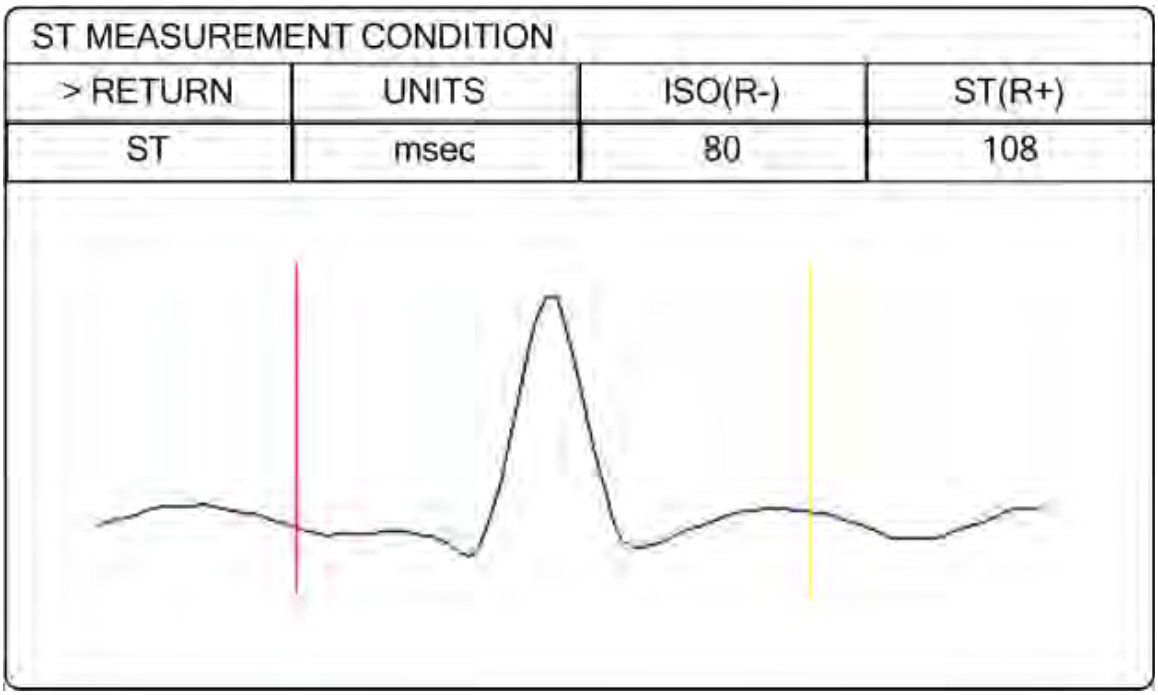


ST ANALYSIS: ON/OFF ST analysis signal.

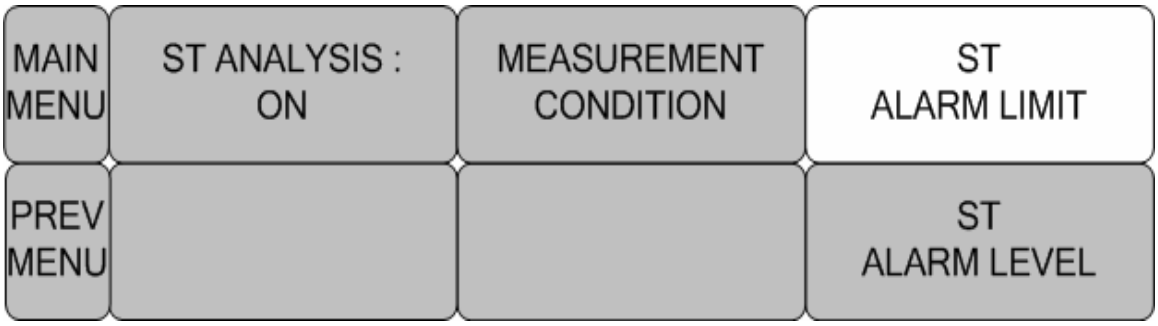
MAIN MENU	ST ANALYSIS : ON	MEASUREMENT CONDITION	ST ALARM LIMIT
PREV MENU			ST ALARM LEVEL

MEASUREMENT CONDITION: ST measurement condition setting

MAIN MENU	ST ANALYSIS : ON	MEASUREMENT CONDITION	ST ALARM LIMIT
PREV MENU			ST ALARM LEVEL



ST ALARM LIMIT: ST alarm limit range setting



ST ALARM LIMIT

> RETURN	UNITS	LOW	HIGH
ST	mm	-20.0	20.0

ST ALARM LEVEL: ALARM LEVEL setting

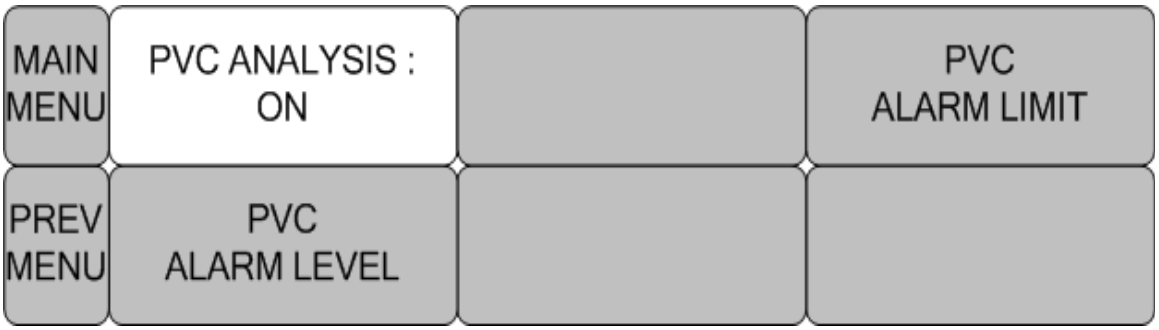
MAIN MENU	ST ANALYSIS : ON	MEASUREMENT CONDITION	ST ALARM LIMIT
PREV MENU			ST ALARM LEVEL

ST ALARM LEVEL	
> RETURN	ST ALARM LEVEL
ST	MEDIUM

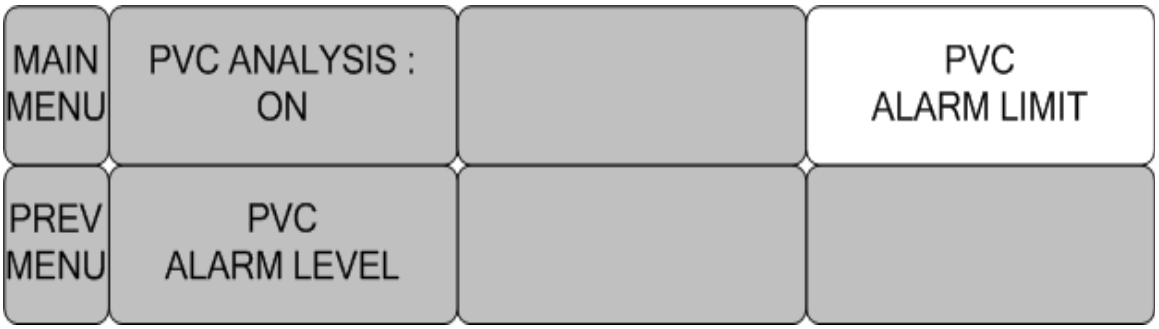
PVC SETTING: PVC ON/OFF and ALARM limit range setting

MAIN MENU	FILTER : MONITOR	PACE : OFF	ARRHYTHM : OFF
PREV MENU		PVC SETTING	ST SETTING

PVC ANALYSIS: Decision maker to display PVC value sign with ON/OFF



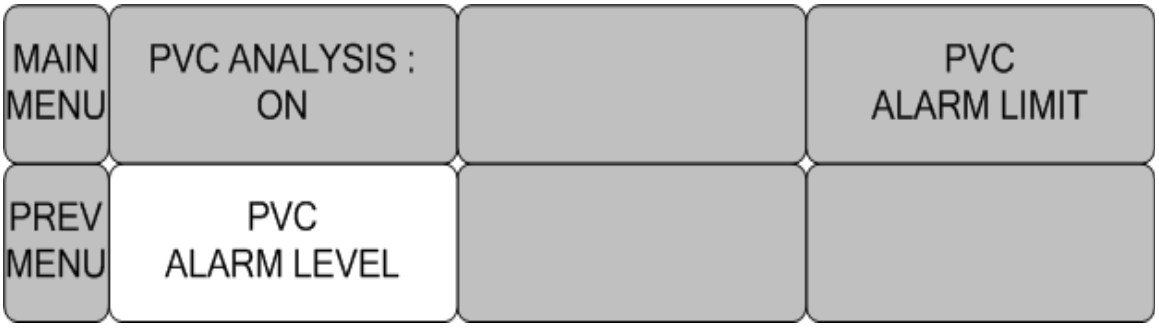
PVC ALARM LIMIT: Set alarm indicate to PVC



PVC ALARM LIMIT

> RETURN	UNITS	LOW	HIGH
PVC Count	/min	0	99

PVC ALARM LEVEL: Set PVC ALARM LEVEL



PVC ALARM LEVEL	
> RETURN	PVC ALARM LEVEL
PVC Count	LOW

Warning
Display Hart Beat Equipment Signal Hart Beat equipment signal displays when the PACE mode is. the signal appears series form. The signal size or form are meaningless clinically **Number Of Heart Beat** Attention to the patient with heart beat equipment. The heart beat equipment can show heart beat even during arrhythmia continuously. Therefore, do not depend on heart beat alarm excessively.

CAUTION

FDA POSTMARKET SAFETY ALERT

The United States FDA Center for Device and Radiological Health issued a safety bulletin October 14, 1998. this bulletin states "that minute ventilation rate-adaptive implantable pacemakers can occasionally interact with certain cardiac monitoring and diagnostic programmed rate."

The FDA further recommends precautions to take into consideration for patients with these types of pacemakers. These precaution for patients with these types of pacemakers. These precautions include disabling the rate responsive mode and enabling an alternate pace mode. For more information contact:

Office of Surveillance and Biometrics, CDRH, FDA
1350 Packard Drive, Mail Stop HFZ-510 Rockville, MD 20850 U.S.A

NOTE

ECG monitoring with patients in non-invasive trans coetaneous pacemakers may not be possible due to large amounts of energy produced by these devices. Monitoring ECG with an external device may be needed.

WARNINGS

VENTRICULAR ARRHYTHMISAS

The arrhythmia analysis program is intended to detect ventricular arrhythmias. It is not designed to detect a trial or supra ventricular arrhythmias. Occasionally it may incorrect identify the presence or absence of an arrhythmia. Therefore, a physician must analyze the arrhythmia information in conjunction with other clinical findings.

SUSPENDED ANALYSIS

Certain conditions suspend arrhythmia analysis. When suspended, arrhythmia conditions are not detected and alarms associated with arrhythmias do not occur. The messages which alert you to the conditions causing suspended arrhythmia analysis are : ARR OFF, ARRHYSUSPEND, LEADS FAIL, ALARM PAUSE, ALL ALARMS OFF, and DISCHARGED.

Trouble shooting

Problem :

Inaccurate heart rate and/or false a systole.

Solution :

Check ECG signal from patient:

1. Check/adjust lead placement.
2. Check/perform skin preparation.
3. Check/replace electrodes.

Check amplitude of ECG waveform:

1. Select ECG parameter label.
2. Select DISPLAY LEAD,
3. Scroll through all ECG leads and check for 0.5mV amplitude at normal (1X) size. (at least 0.5mV amplitude is required for QRS detection.) for borderline signals, validate on a graph.
4. If amplitudes are low, electrodes may need to be repositioned or replaced.

Problem :

False ventricular calls.

Solution :

Check ECG signal from patient: (the chest lead may exhibit polarity changes which may occasionally cause an inaccurate call.)

1. Check/adjust lead placement.
2. Check/perform skin preparation.
3. Check/replace electrodes. (if chest lead is a problem, move the chest lead to another chest position or leg position.)

Problem :

Inaccurate pacemaker detection

Solution :

Use pacemaker processing:

1. Select ECG parameter label.
2. Display the lead of ECG with the greatest amplitude in the top waveform position.
3. Select ANALYSIS SETTINGS.
4. SELECT DETECT PACE.

6. SpO_2

6.1 Outline

SpO_2 Connector Location and Measuring Cable

6.2 SpO2 Data Window

6.3 SpO2 Data Setup

SWEEP SPEED

RATE VOLUME

ALARM

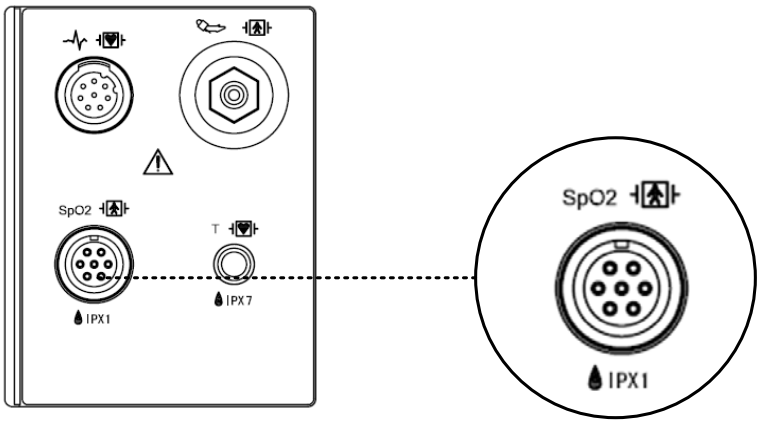
ALARM LIMIT

6.1 Outline

SPO2 monitoring is a noninvasive technique used to measure the amount of oxygenated hemoglobin and pulse rate by measuring the absorption of selected wavelengths of light. The light generated in the probe passes through the tissue and is converted into an electrical signal by the photodetector in the probe. The monitor processes the electrical signal and displays on the screen a waveform and digital values for SpO2 and pulse rate. It detects SpO2 in the way of transmitting the red and infrared rays into the capillary vessel to take the pulsation. Also perform the alarm function according to the setting value.

SpO2 Connector Location and Measuring Cable

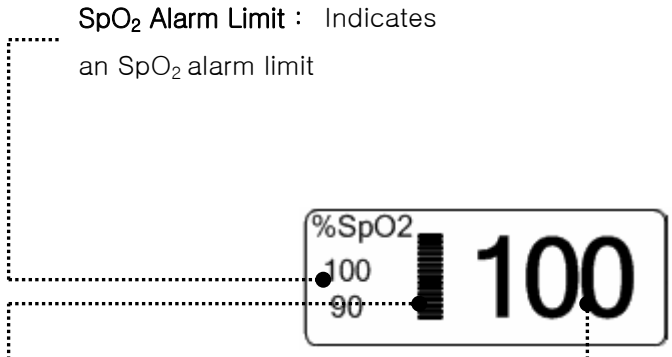
SpO_2 connector



SpO_2 Measuring Cable

Note
The signal input is a high-insulation port and it is defibrillator proof ( )   The insulated input ensures patient safety and protects the device during defibrillation and electrosurgery.

6.2 SpO_2 Data Window



SpO_2 Alarm Limit : Indicates an SpO_2 alarm limit

SpO_2 Strength indicators : Indicates SpO_2 Strength in a bar graph.

Oxygen Concentration in the Blood(SpO2 value) : Indicates $\%SpO_2$ in numbers.

The current SPO2 value and the derived pulse rate (RATE) are displayed. The block sets indicate the strength of the signal (twenty block bars indicate the strongest signal). The SPO2 measurements are averaged over a 6-second period of time.

The monitor display is updated every second.

The SPO2 monitoring features are found in the SPO2 menu. These features include alarm limit adjustment, display of RATE, and RATE volume.

Note
SpO_2 WAVE SIZE is changed automatically.

Signal and Data Validity

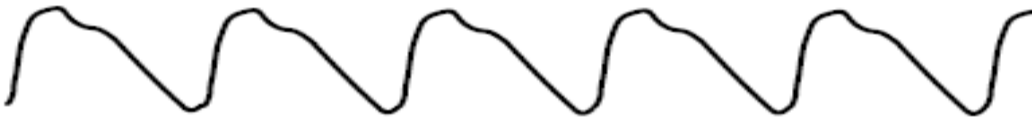
It is extremely important to determine that the probe is attached to the patient correctly and the data is verifiable. To make this determination, three indications from the monitor are of assistance—signal strength bar, quality of the SPO2 waveform, and the stability of the SPO2 values. It is critical to observe all three indications simultaneously when ascertaining signal and data validity.

Signal Strength Bar

The signal strength bar is displayed within the SPO2 values window. This bar consists of 20 blocks set depending on the strength of the signal. Proper environmental conditions and probe attachment will help to ensure a strong signal.

Quality of SPO2 Waveform

Under normal conditions, the SPO2 waveform corresponds to (but is not proportional to) the arterial pressure waveform. The typical SPO2 waveform indicates not only a good waveform, but helps the user find a probe placement with the least noise spikes present. The figure below represents an SPO2 waveform of good quality.



Good Quality SPO2 Waveform

If noise (artifact) is seen on the waveform because of poor probe placement, the photodetector may not be flush with the tissue. Check that the probe is secured and the tissue sample is not too thick. Pulse rate is determined from the SPO2 waveform which can be disrupted by a cough or other hemodynamic pressure disturbances. Motion at the probe site is indicated by noise spikes in the normal waveform. (See the figure below.) It has been noted that letting the patient view the SPO2 waveform enables them to assist in reducing motion artifact.

SPO2 Waveform with Artifact

Stability of SPO2 Values

The stability of the displayed SPO2 values can also be used as an indication of signal validity. Although stability is a relative term, with a small amount of practice one can get a good feeling for changes that are artifactual or physiological and the speed of each. Messages are provided in the SPO2 values window to aid you in successful SPO2 monitoring.

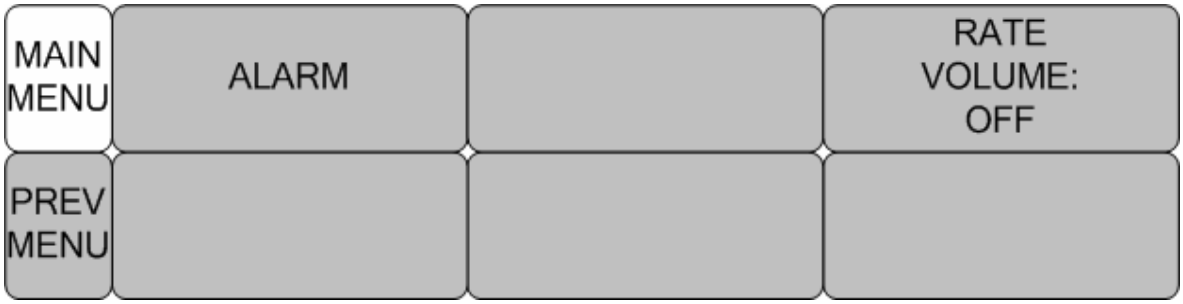
WARNING
In the monitoring of patients the coincidence of adverse conditions may lead to a disturbed signal going unnoticed. In this situation artifacts are capable of simulating a plausible parameter reading, so that the monitor fails to sound an alarm. In order to ensure reliable patient monitoring, the proper application of the probe and the signal quality must be checked at regular intervals.

6.3 SpO_2 Data Setup

ALARM LIMIT： Menu in which SpO_2 limits are set up.

SWEEP SPEED: speed SpO2 Waveform display setting menu

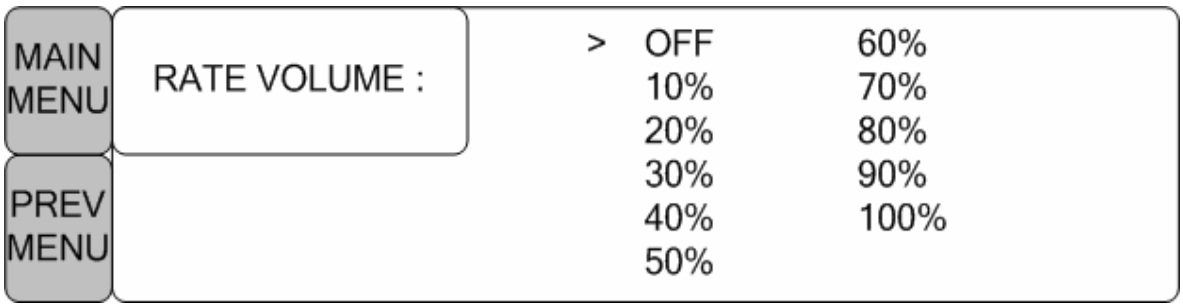
RATE VOLUME：Menu in which RATE VOLUME is set up



RATE VOLUME

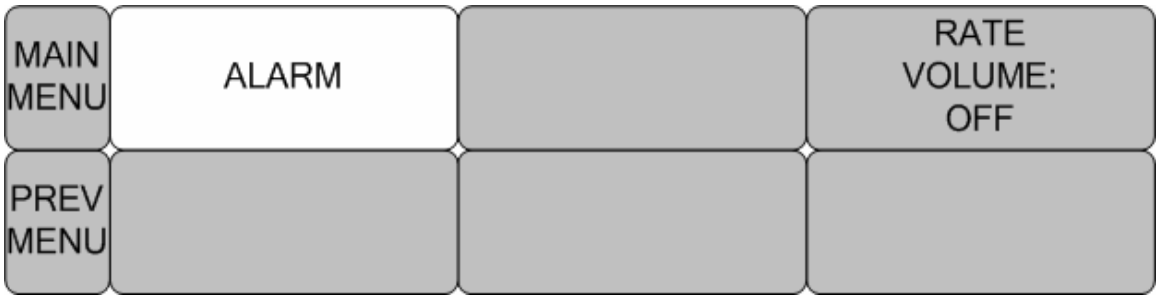
Move the KEY to select the volume from OFF to 100%.

When the ECG volume rate is set, it turns OFF automatically.



ALARM

Two menus: ALARM LIMIT, ALARM provided in the alarm menu



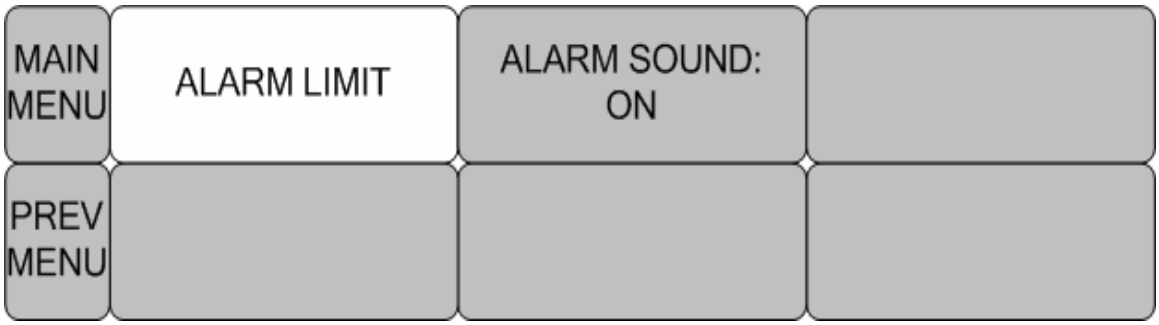
ALARM LIMIT

Number setting of alarm value of %SpO_2 is 0 ~ 100

1. Move the mark to select from RETURN, SpO_2 or SpO_2-R, and press.
2. After pressing at SpO_2, move the cursor right or left to LOW, and press.
3. Once the color is changed, move the cursor again to the selected value and press.
4. Place the cursor to HIGH and press, when the color changes, move the cursor again to select the targeted value, and press. Finally move to SpO_2 and press.

(You may decide to perform the process in the opposite order, LOW to HIGH, to have the same result.)

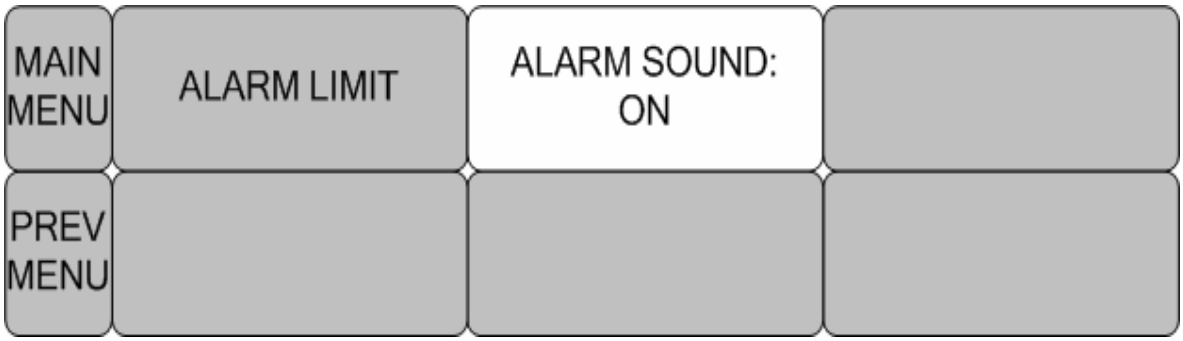
5. After pressing at SpO_2-R, move the cursor right or left to LOW, and press.
6. Once the color is changed, move the cursor again to the selected value and press.
7. Place the cursor to HIGH and press, when the color changes, move the cursor again to select the targeted value, and press. Finally move to SpO_2-R and press.
8. With the selection of RETURN the user gets out of the menu.

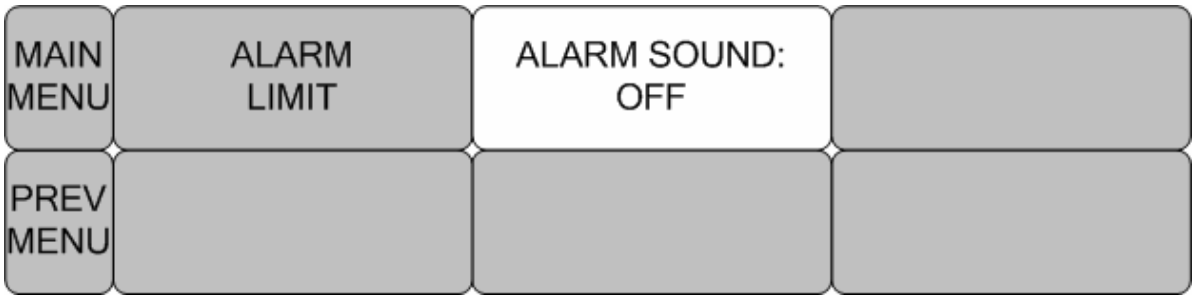


SPO2 ALARM LIMIT			
RETURN	UNITS	LOW	HIGH
SPO2-%	%	90	100
SPO2-R	BPM	50	150

ALARM SOUND

Warning sound or message displays configuration menu when an alarm is triggered.





LEAD FAULT Condition

When using a reusable finger probe, there is a system alarm to alert you when the probe is off the Monitor. The monitor defaults this " LEAD FAULT" condition as a System Warning alarm. however, You can set it as a System ALARM LEVEL in Monitor Defaults.

SPO2 Messages

Below is a list of system status alarm messages which may be displayed in the SPO2 parameter window during monitoring.

CHECK PROBE

Reusable finger probe is off the patient. Check the probe. *The factory default for this alarm is MESSAGE ALARM.*

PULSE SEARCH

Detection by the monitor of a repeatable pulse has ceased. Check the patient and the probe site.

POOR SIGNAL

The SPO2 signal is too low. No SPO2 data is displayed. This can be due to a low patient pulse, patient motion, or some other interference. Check the patient and the probe.

LOST SIGNAL

SPO2 data continues to be displayed, but the quality of the signal is questionable. Check the patient and the probe.

7. RESPIRATION

7.1 Outline

Respiration Connector and Measuring Cable

7.2 RESPIRATION Data Window

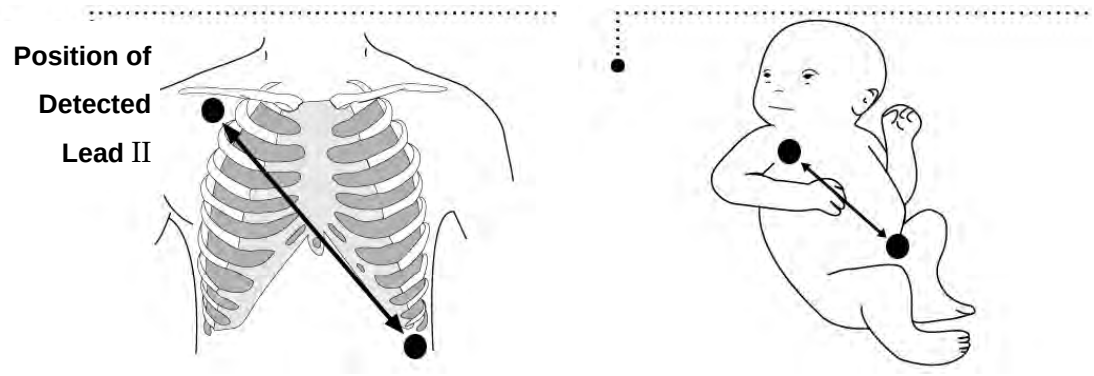
7.3 RESPIRATION Data Setup

Respiration Size

Alarm Limit

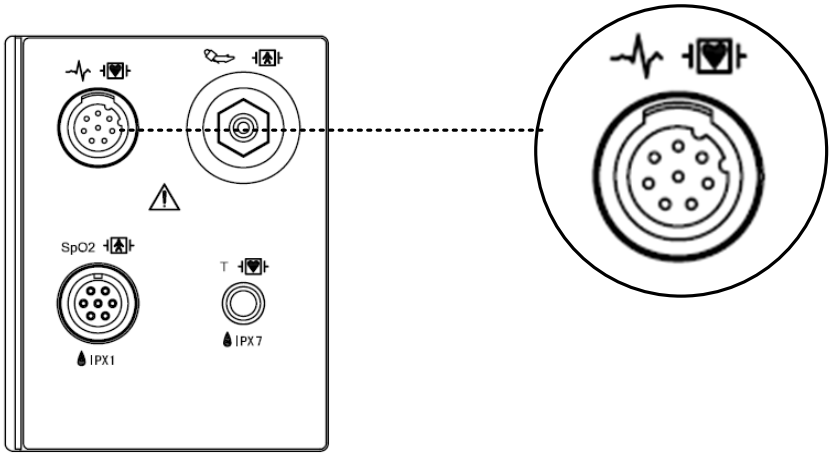
7.1 Outline

Respiration via ECG Lead II electrode makes the skin area of the chest enlarged, causing changes in the resistance of skin. Through this it calculates respiration value per minutes and performs the alarm function according to limit value.



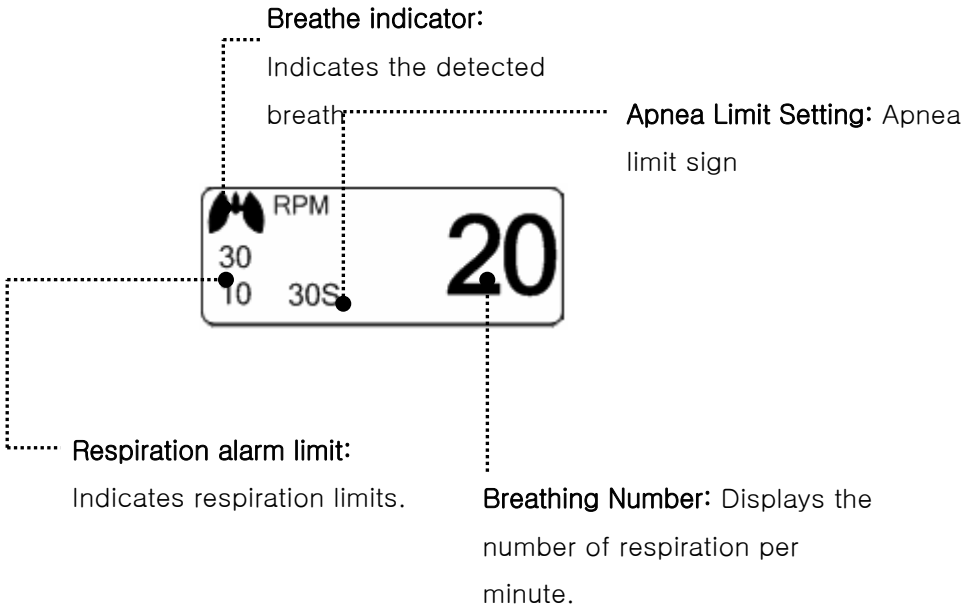
Respiration Connector and Measuring Cable

Respiration Connecter



Respiration
Measuring Cable

7.2 Respiration Data Window



7.3 Respiration Data Setup

ALARM: Respiration alarm setting menu

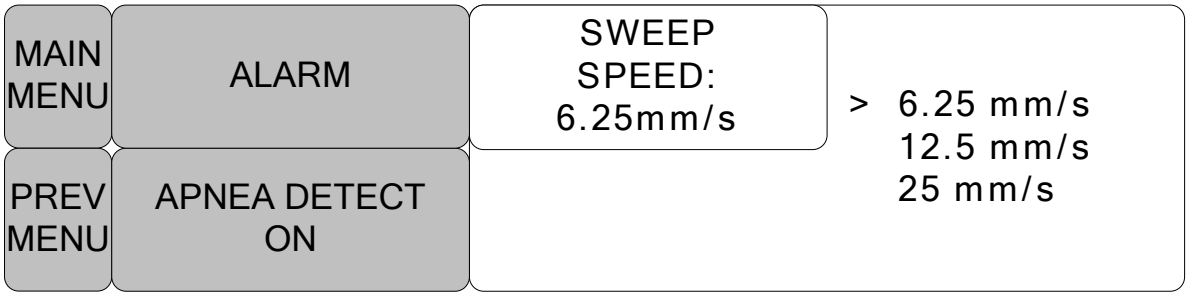
RESP SIZE: A menu to setup Wave Display

SWEEP SPEED: A menu to setup Wave Display of speed

APNEA DETECT: A menu to setup APNEA alarm display

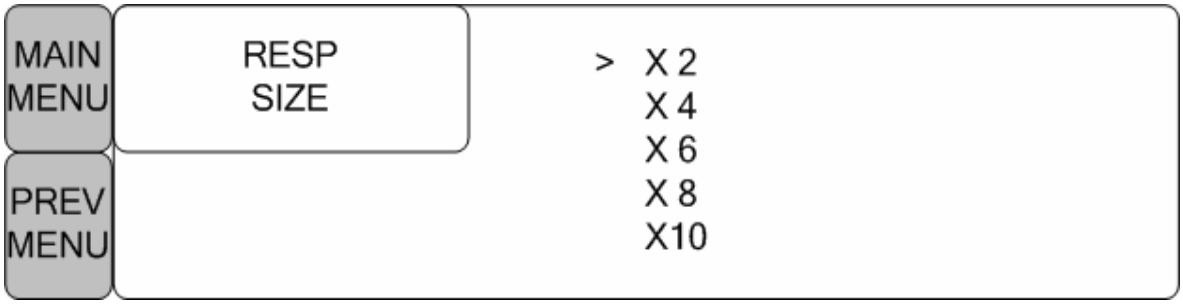
RESPIRATION SPEED

Wave pattern speed is 25 mm/s.



RESPIRATION

Set wave pattern size X2~ X10.

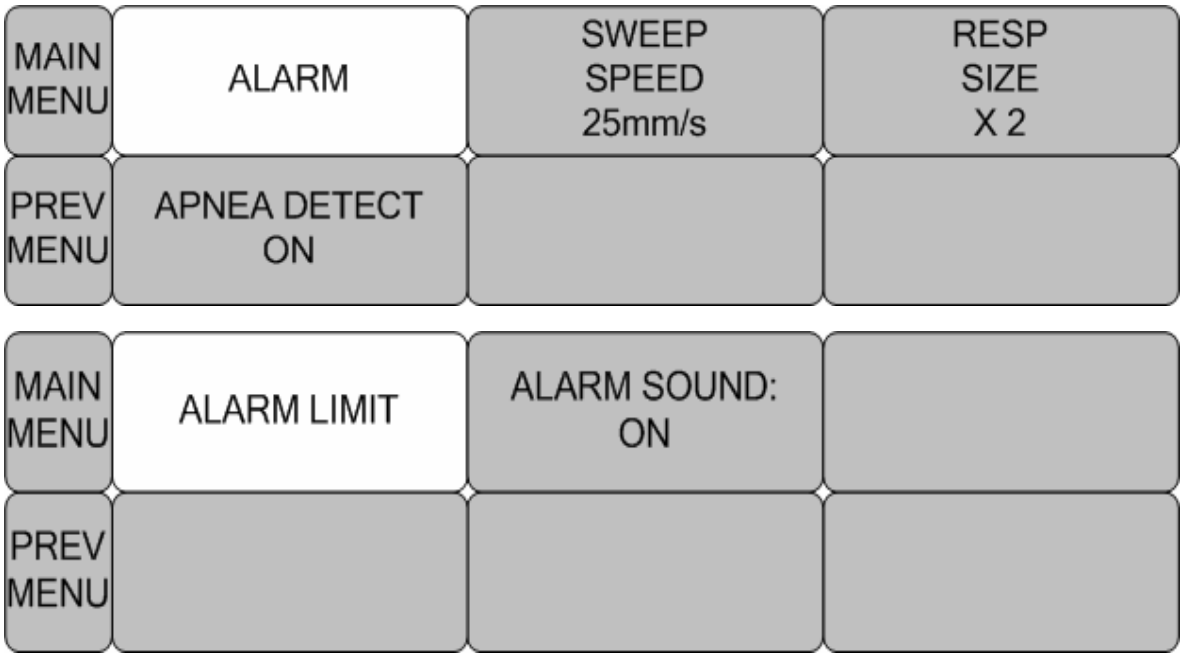


APNEA DETECT

Deciding function of activating Apnea Alarm

ALARM

Alarm menu provide ALARM LIMIT and ALARM.



ALARM LIMIT

Alarm Limit of Respiration Numeric Value is 5 ~ 150bpm

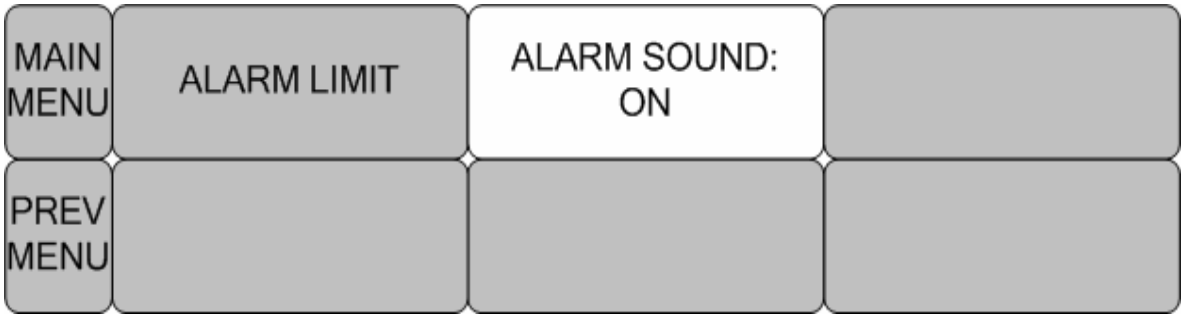
Alarm Limit of RESPIRATION APNEA Numeric Value is 3 ~ 30sec.

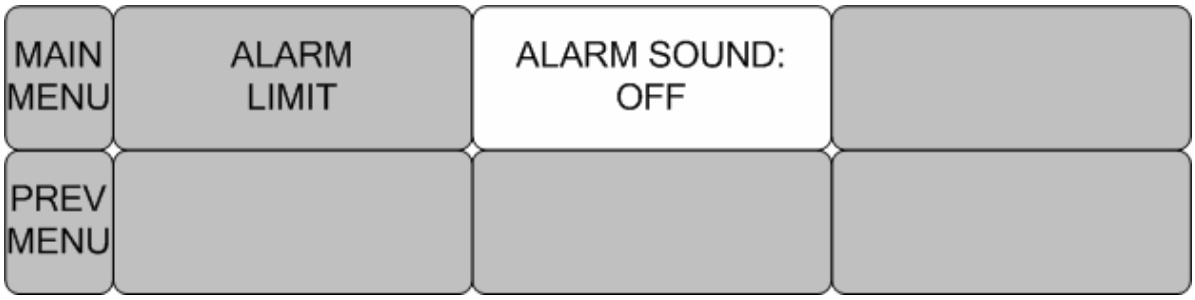
1. Move the mark to select RETURN, RESP or RESP-A, and press.
2. After a press in RESP, move the cursor right or left to LOW, and press.
3. After the color changed, move the cursor right or left to the selected value, and press.
4. Place the cursor to HIGH, and press. When the color has changed, move the cursor again to select the value and press. Move to the RESP and press again. (You may decide to perform the process in the opposite order, LOW to HIGH, to have the same result.)
5. Once RESP-A is pressed, move to LOW and press.
6. When the color has changed, move the cursor to select the value, and press.
7. A press in the HIGH position, the color changes. Then move the cursor to select the value and press. Move again to RESP-A, and press.
8. Select RETURN to get out of the window.

RESP ALARM LIMIT			
RETURN	UNITS	LOW	HIGH
RESP	RPM	10	30
RESP-A	SEC	0	20

ALARM SOUND

Warning sound or message displays activation setting when Respiration ALRAM occurs.





8. NIBP

8.1 Outline

NIBP Connector Location and Cuff

8.2 NIBP Data Window

8.3 NIBP Data Setup

ALARM LIMIT

ALARM

CUFF SIZE

UNIT SELECT

INTERVAL

STAT

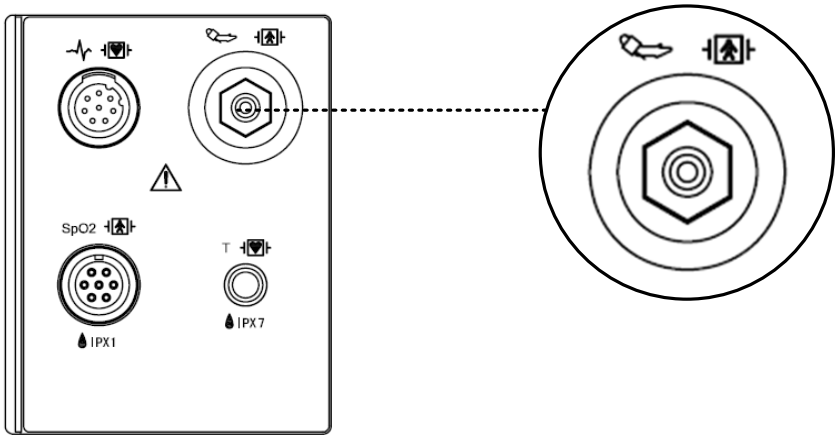
INFLATION

8.1 Outline

This function is to measure minimum, Maximum and average blood pressure by using Oscillometric method

Position of NIBP Connecter and cuff

NIBP Connector



Note
As the value of NIBP can vary according to the age and sex of a patient, the user needs to set up right data in Parameter Menu before measurement.

WARNING
Noninvasive blood pressure monitoring is not recommended for patients with hypotension, hypertension, arrhythmias or extremely high or low heart rate. The software algorithm cannot accurately compute NIBP or patients with these conditions.

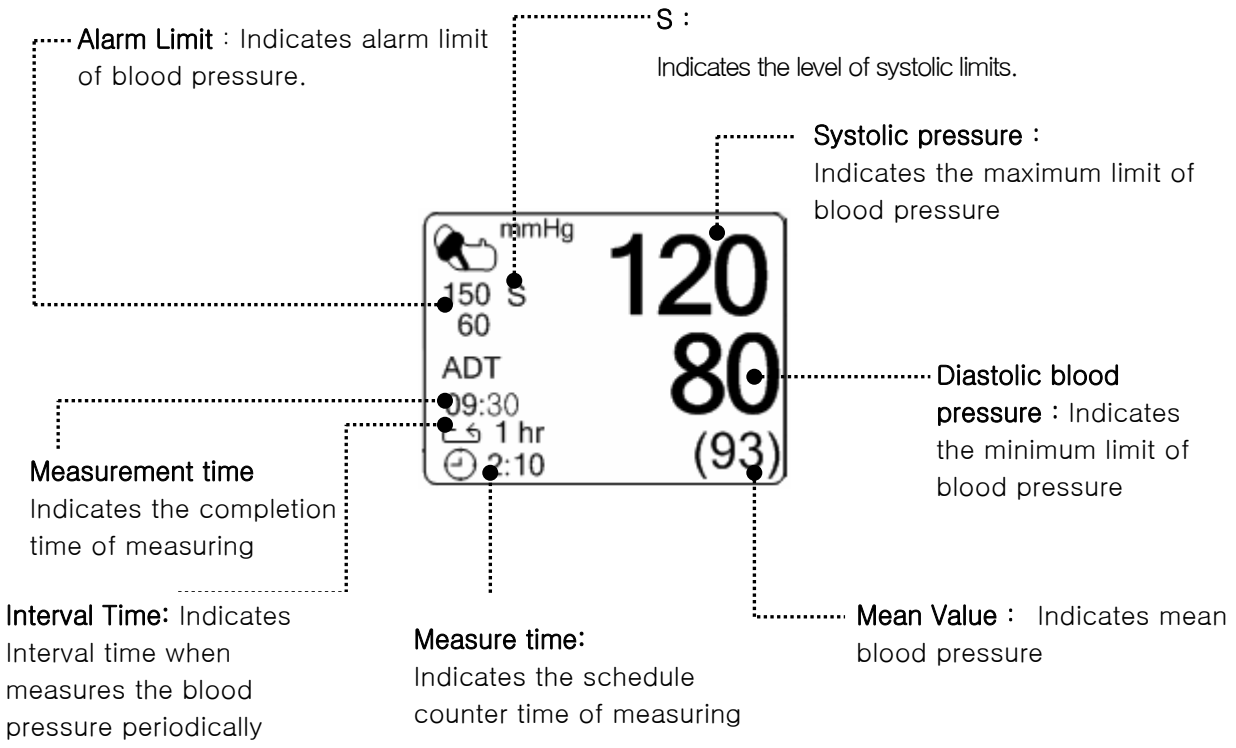
Note
As the value of NIBP can vary according to the age and sex of a patient, the user needs to set up right data in parameter Menu before measurement. Tubes between the cuff and the monitor are not kinked or blocked. The air pad should be exactly over the branchial artery. Tubing is immediately to the right or left of the branchial artery to prevent kinking when elbow is bent.

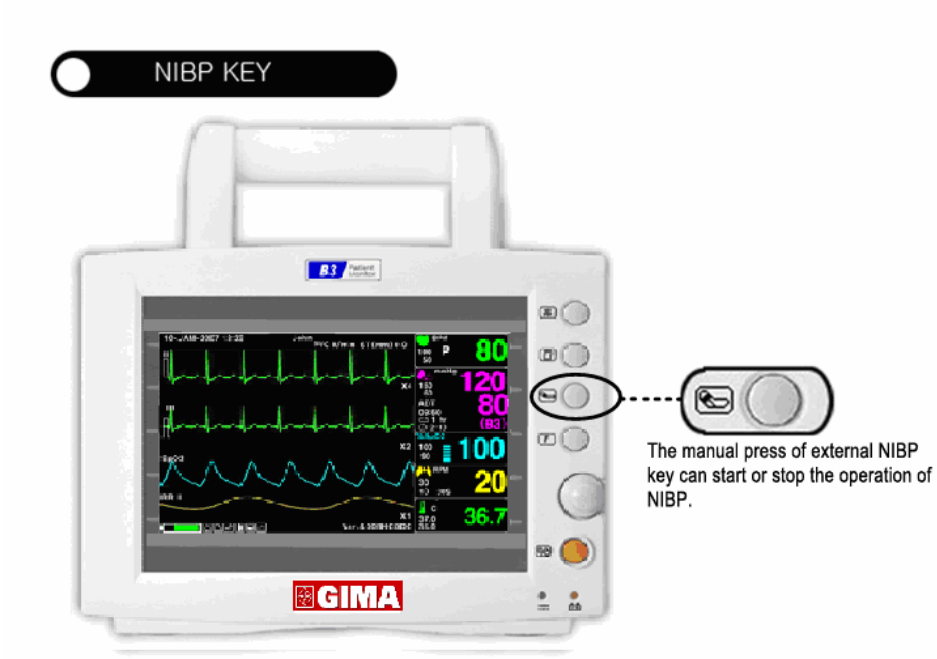
The maintenance is performed every 2 years.

Check the following list devise to operates properly and safety at all times.

1. Check for proper cuff size.
2. Check for residual air left in the cuff from a previous measurement.
3. Make sure cuff is not too tight or too loose.
4. Make sure cuff and heart are at same level, otherwise hydrostatic pressure will offset the NIBP value.
5. Minimize patient movement during measurement.
6. Watch for pulses paradox us.
7. Check for leak in cuff or tubing.
8. Patient may have a weak pulse.

8.2 NIBP Data Window





8.3 NIBP Data Setup

ALARM： A menu to set the Alarm

CUFF SIZE：A menu to select cuff size

UNIT SELECT: A menu to select the pressure unit

INTERVAL ：A menu to set Interval time when measures the blood pressure periodically

STAT: a menu to set activation of 5 minute spontaneous monitor mode

INFLATION: Initial Pressurization setting menu

MAIN MENU	ALARM	STAT: ON	CUFF SIZE: ADT
PREV MENU	UNIT SELECT: mmHg	INFLATION: 140mmHg	INTERVAL: OFF

ALARM

The alarm provides ALARM LIMIT and ALARM.

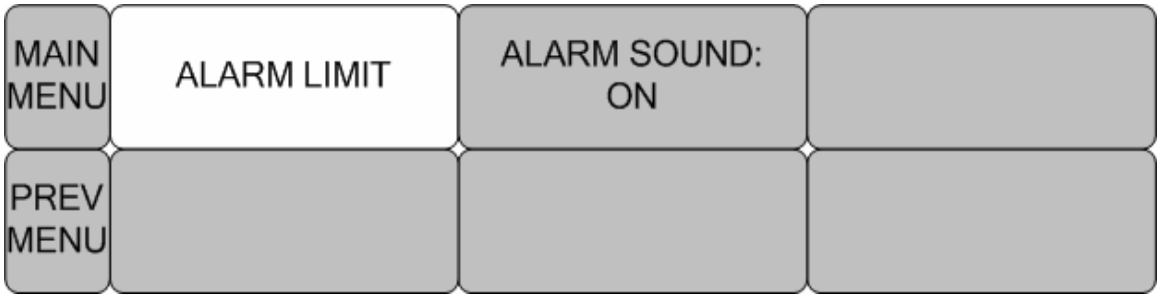
MAIN MENU	ALARM	STAT: ON	CUFF SIZE: ADT
PREV MENU	UNIT SELECT: mmHg	INFLATION: 140mmHg	INTERVAL: OFF

MAIN MENU	ALARM LIMIT	ALARM SOUND: ON	
PREV MENU			

ALARM LIMIT

Alarm setting Numeric Value of Systolic, Diastolic, and mean pressure is 10 ~ 360mmHg.

1. Move the mark to select one from RETURN, NIBP-S, NIBP-M, or NIBP-D, and press.
2. Press the key at NIBP-S, and move to LOW, and press again.(The user gets the same result regardless of the LOW-HIGH, or HIGH-LOW order.)
3. When the color has changed, move it again to select a target value, and press.
4. Press the key at HIGH. When the color has changed, move to the right to select a target value, and press.
5. Set up or revise the values of NIBP-M and NIBP in the same way as above.
6. With the selection of RETURN, the user can get out of the window.

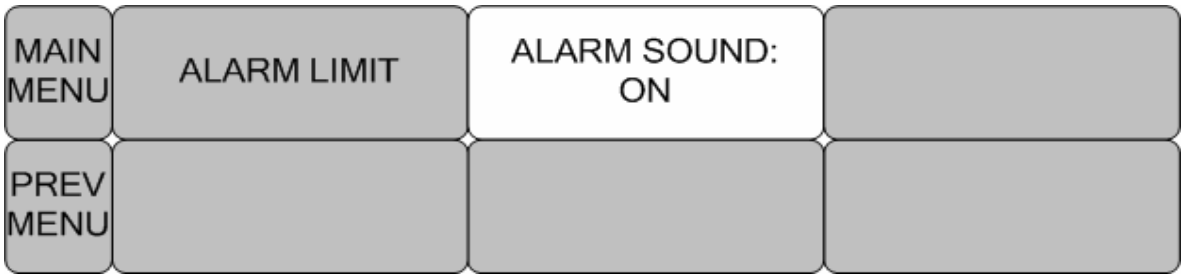


NIBP ALARM LIMIT

RETURN	UNITS	LOW	HIGH
NIBP-S	mmHg	80	200
NIBP-M	mmHg	40	140
NIBP-D	mmHg	20	120

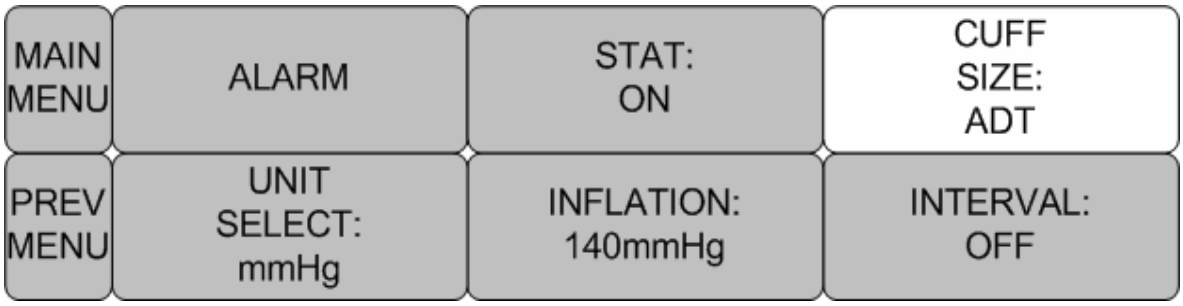
ALARM SOUND

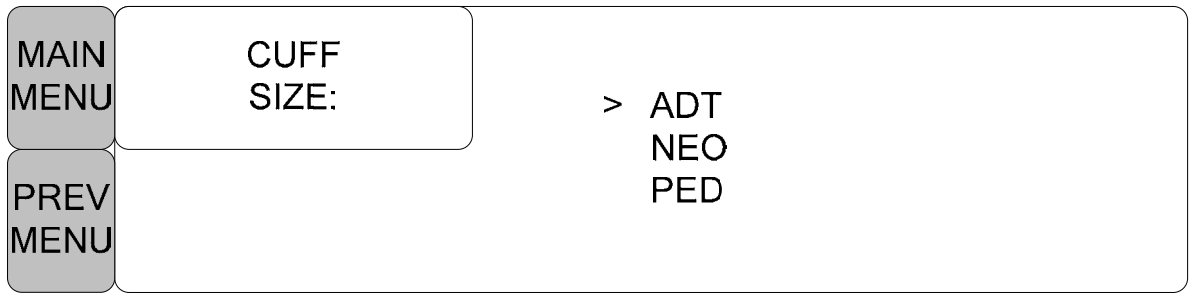
The menu which decide activate of warning sign and message display when the respiration alarm is on.



CUFF SIZE

The user can select a CUF between ADULT and NEONATAL.





UNIT SELECT

It is a function to set blood pressure measurement unit.

The blood pressure measurement unit provides mmHg and kPa.

MAIN MENU	ALARM	STAT: ON	CUFF SIZE: ADT
PREV MENU	UNIT SELECT: mmHg	INFLATION: 140mmHg	INTERVAL: OFF

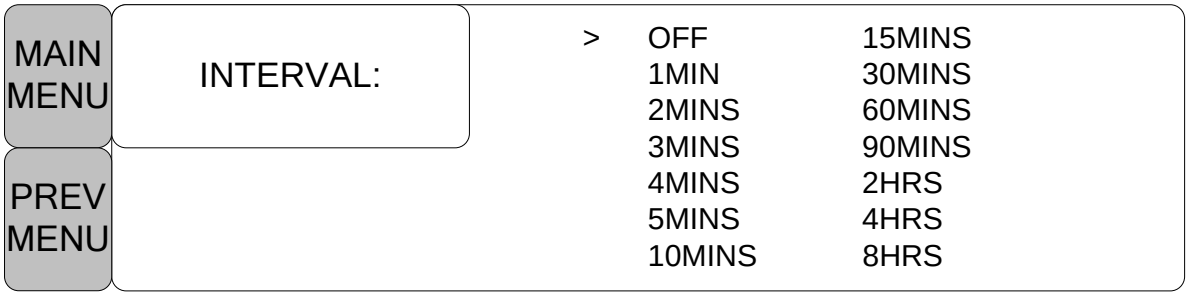
MAIN MENU	ALARM	STAT: ON	CUFF SIZE: ADT
PREV MENU	UNIT SELECT: kPa	INFLATION: 140mmHg	INTERVAL: OFF

INTERVAL

This menu is used for selecting intervals when measures the blood pressure automatically.

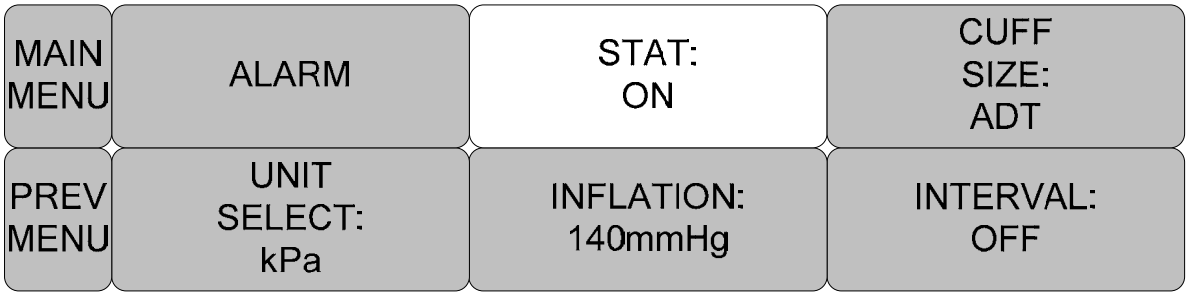
Select a target interval from 1min, 2, 3, 4, 5, 10, 15, 20, 30, 1hour, 2, 4, 8.

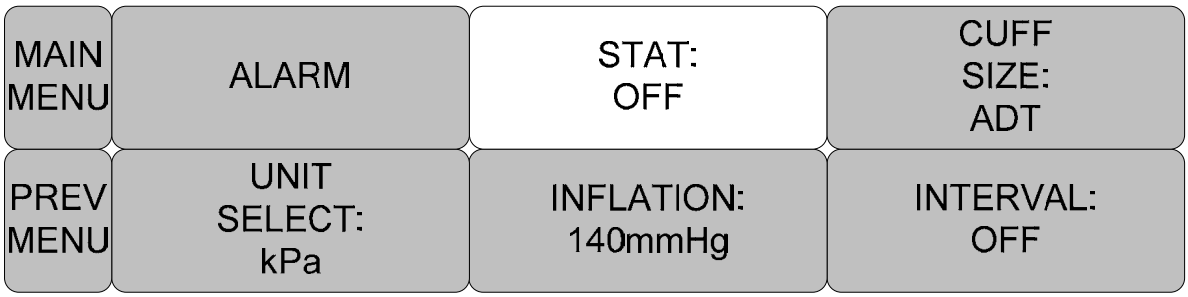
MAIN MENU	ALARM	STAT: ON	CUFF SIZE: ADT
PREV MENU	UNIT SELECT: kPa	INFLATION: 140mmHg	INTERVAL: OFF



STAT

5 minute monitoring mode activates spontaneously when STAT mode is on.

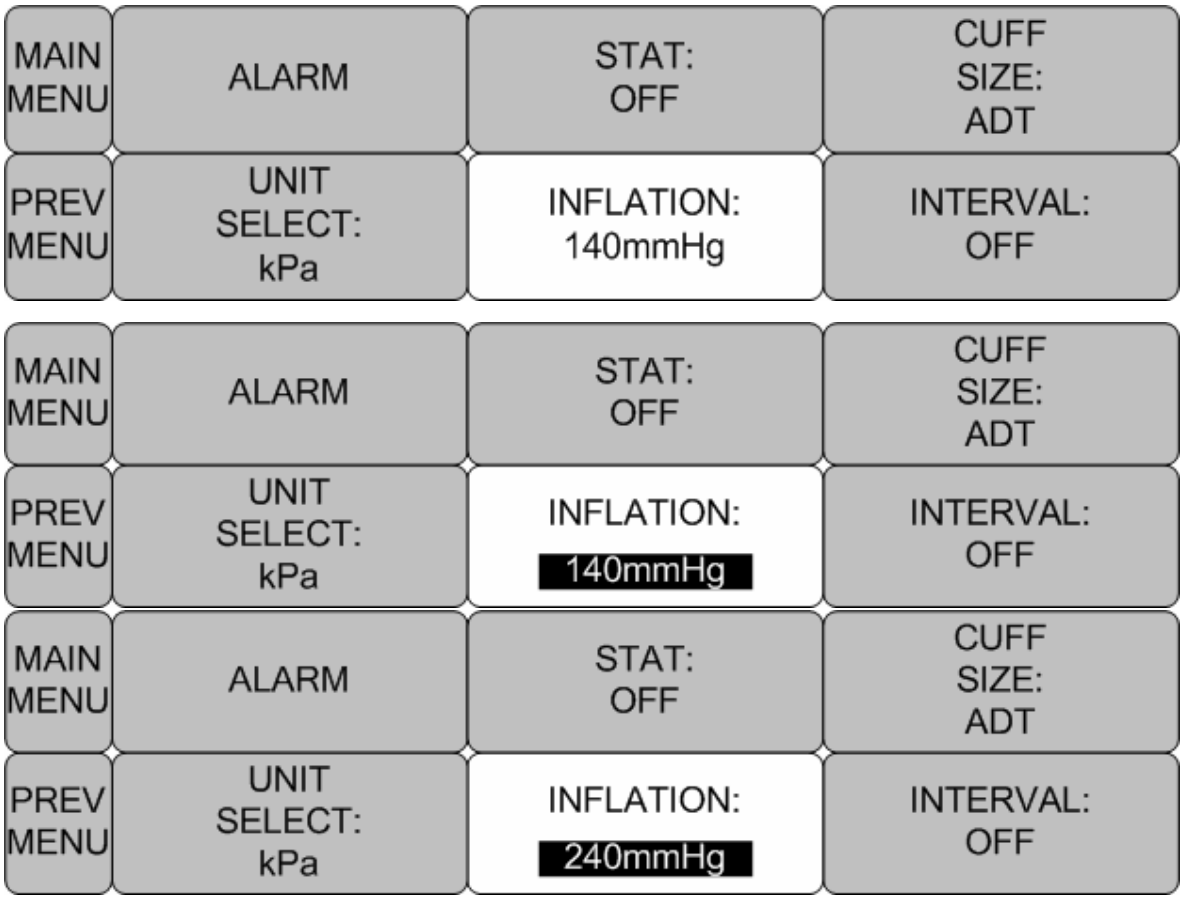




INFLATION

It is a function for pressurization pressure.

Numeric value is 80, 100, 120, 140, 160, 180, 200, 220, and 240.



Warning
Pay attention to not to block connecting hose when you put cuff on patient.

9. TEMPERATURE

9.1 Outline

Temperature Connector and Measuring Cable

9.2 Temperature Data Window

9.3 Temperature Data Setup

ALARM LIMIT

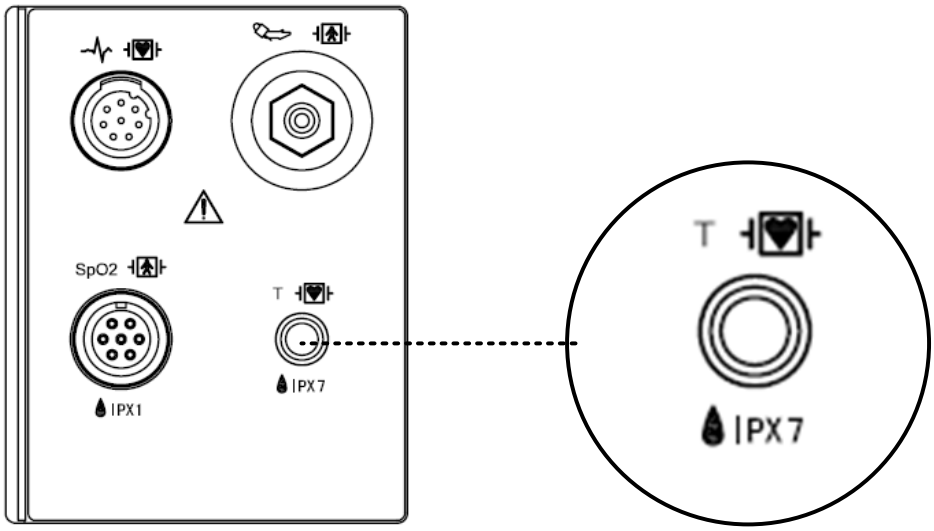
UNIT SELECT

9.1 Outline

This function is used to indicate the changes of resistance generated by the changes of temperature in numbers. The function involves the process of transferring the changes into electric signals.

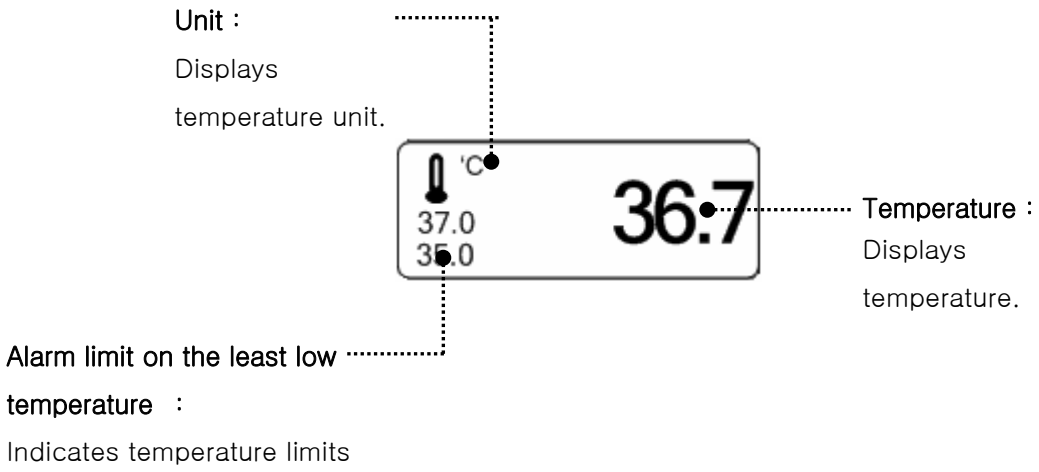
Temperature Connector and Measuring Cable

Temperature Connector



Note
Temperature probe is correctly positioned and fixed to do not disconnect on the patient. Temperature cable is attached to the monitor.

9.2 Temperature Data Window

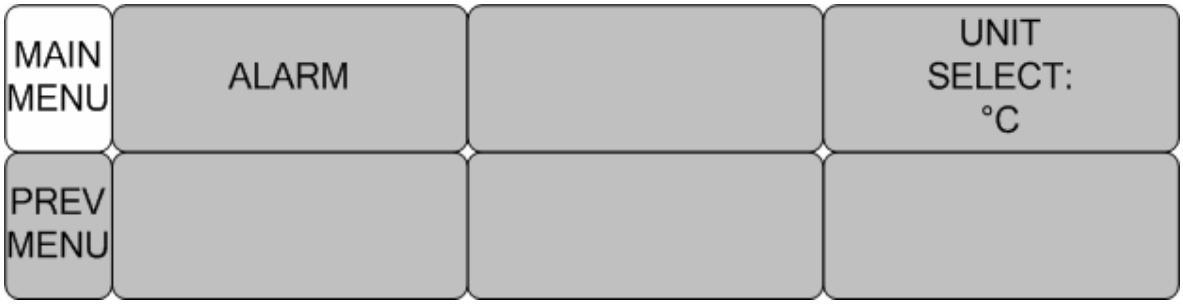


Note
The minimum measuring time required to obtain accurate readings at the specific body site is at least 3 minutes.

9.3 Temperature Data Setup

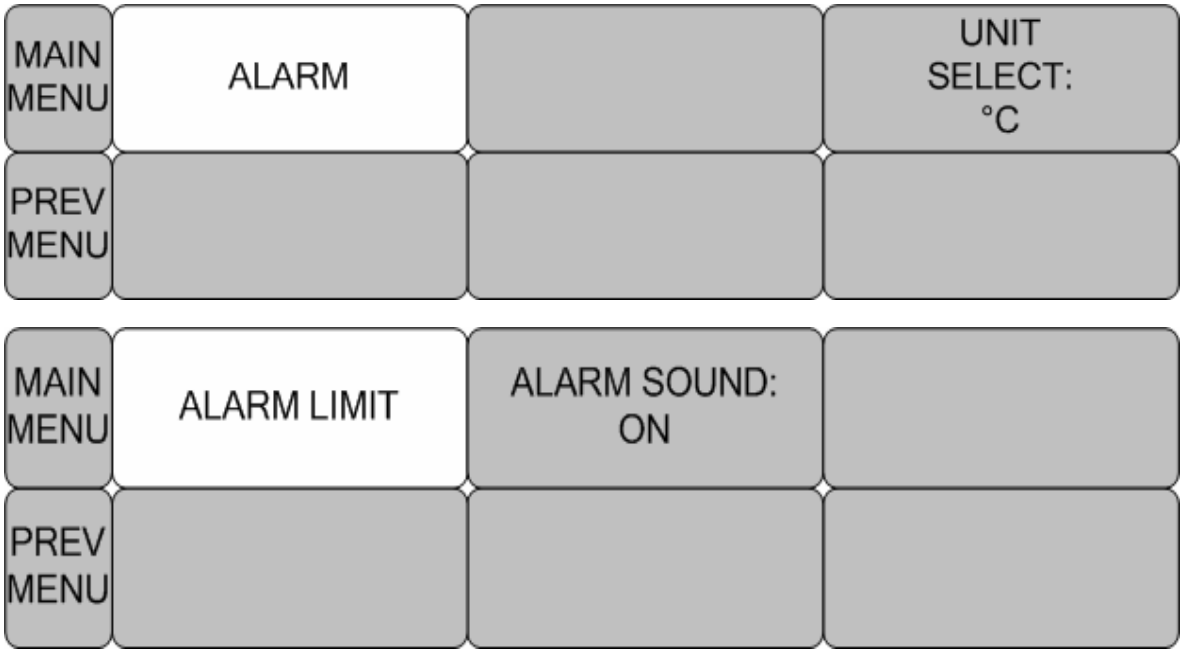
ALARM： Temperature measurement alarm set

UNIT: Temperature measurement unit set



ALARM

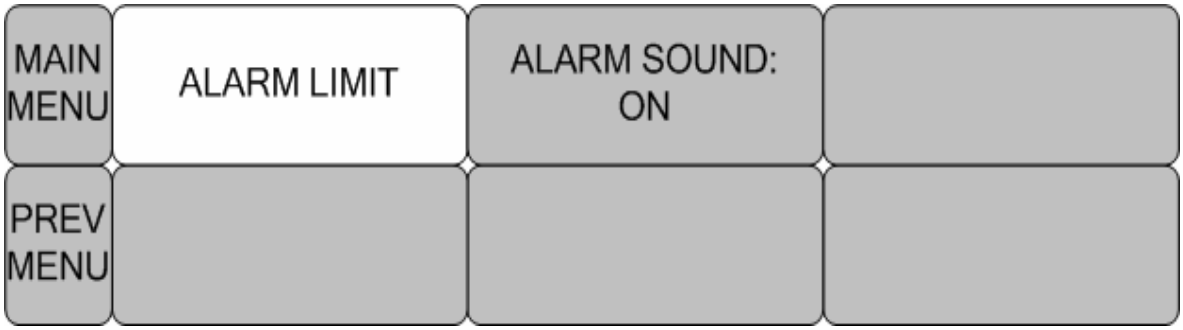
Alarm menu provide ALARM LIMIT and ALARM.



ALARM LIMIT

Setting numeric value is 15.0 ~ 45.0 .

1. Move the mark to select either RETURN or TEMP, and press.
2. After pressing the cursor at TEMP, move it to LOW, and press.
3. When the color has changed, move the cursor again to select a target value, and press.
4. Move the cursor to HIGH and press. After the color has changed, move the cursor again to select a target value, and press. (One may choose HIGH first to get the same result.)
5. Select RETURN to get out of the menu.

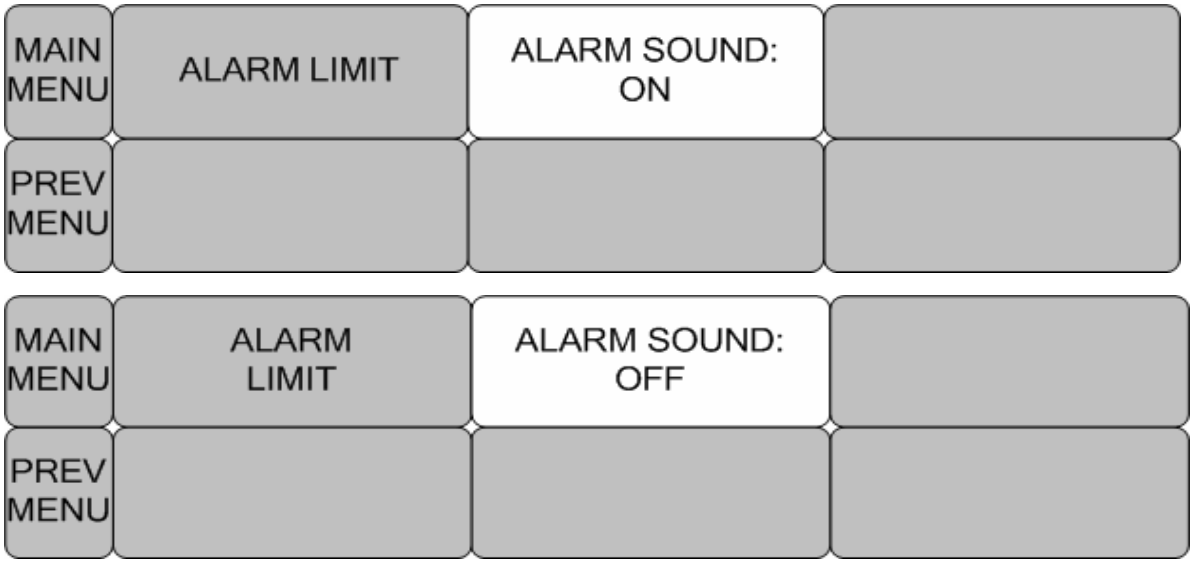


TEMP ALARM LIMIT

RETURN	UNITS	LOW	HIGH
TEMP	°C	30.0	42.0

ALARM SOUND

The menu which decide activate of warning sign and message display when the respiration alarm is on.



UNIT SELECT

Able to select unit with °C, °F.

10. PRINT

10.1 Print

Printer and Heat Sensitivity Paper

Function and Setup Menu

10.2 Paper Change

10.1 Print

Printer and Heat Sensitivity Paper

A printer used to print data onto thermal paper, this product is offered as an option.

Size of the thermal paper roll: 580mm wide x 380mm in diameter any thermal paper of same size can be used for the printer.

Side View of Printer

Function and Setup Menu

MAIN MENU	PRINTER SPEED: 25mm/s		WAVE FORM1: ECG
PREV MENU	WAVE FORM2: SPO2	WAVE FORM3: RESP	

1. Press the PRINT Key for continuous printing.

2. Select Printing Speed 25, 50 mm/s.

MAIN MENU	PRINTER SPEED: 25mm/s		WAVE FORM1: ECG
PREV MENU	WAVE FORM2: SPO2	WAVE FORM3: RESP	

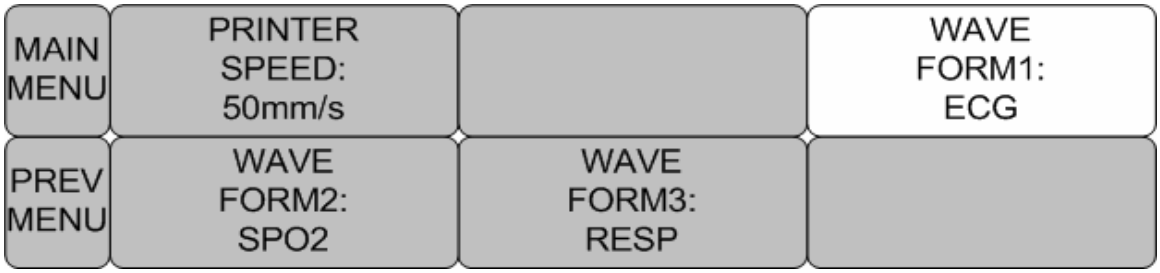
MAIN MENU	PRINTER SPEED: 50mm/s	WAVE FORM1	WAVE FORM2
PREV MENU	WAVE FORM3		

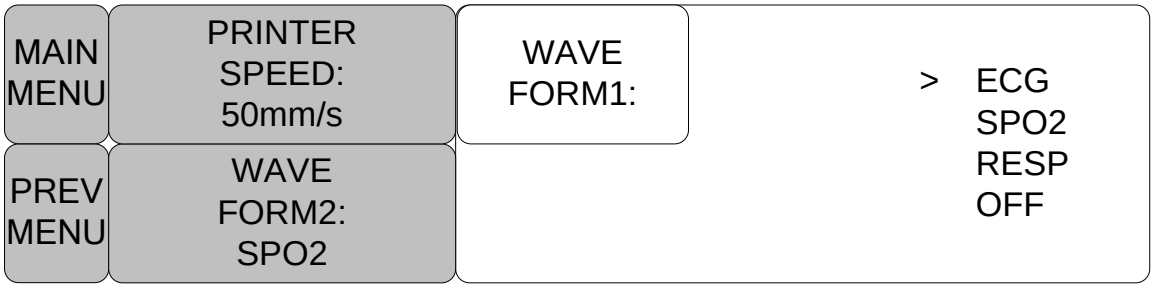
3. Set up ALARM PRINT in the MORE menu to activate ALARM during printing.

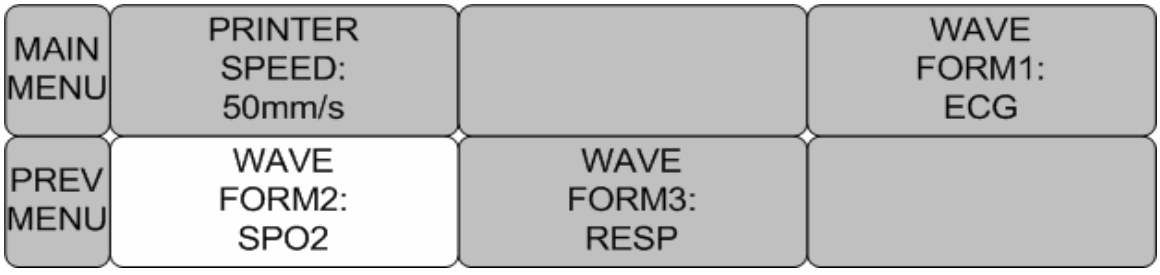
⇨ **ALARM** ⇨ **ALARM PRINT** ⇨ **ON**

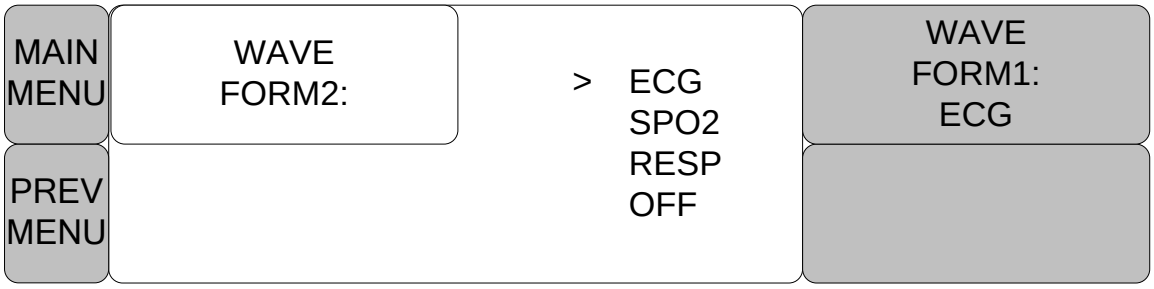
4. Data is printed in a selected wave form along with personal information of the patient.
   3 channels select 3 parameters to print.

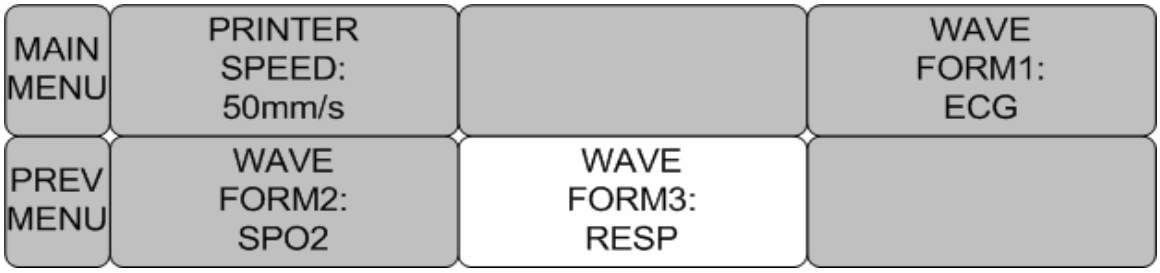
⇨ **PRINTER** ⇨ **ECG,** RESP, SPO2

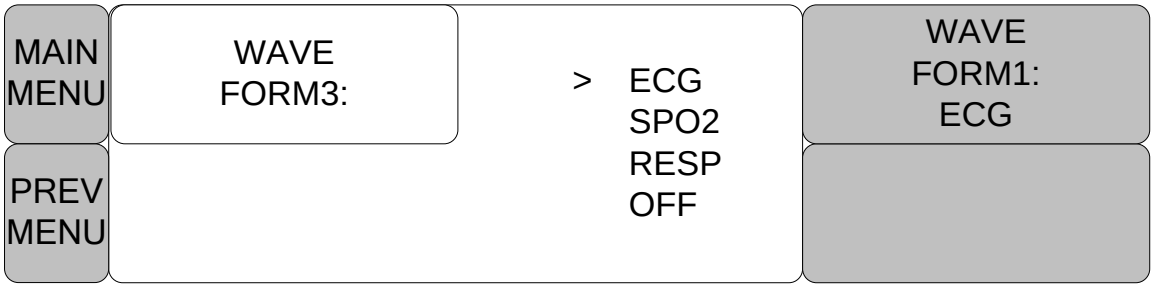

MAIN MENU
PRINTER SPEED: 50mm/s
WAVE FORM1: ECG
PREV MENU
WAVE FORM2: SPO2
WAVE FORM3: RESP


MAIN MENU
PRINTER SPEED: 50mm/s
WAVE FORM1:
> ECG
SPO2
RESP
OFF
PREV MENU
WAVE FORM2: SPO2


MAIN MENU
PRINTER SPEED: 50mm/s
WAVE FORM1: ECG
PREV MENU
WAVE FORM2: SPO2
WAVE FORM3: RESP


MAIN MENU
WAVE FORM2:
> ECG
SPO2
RESP
OFF
WAVE FORM1: ECG
PREV MENU


MAIN MENU
PRINTER SPEED: 50mm/s
WAVE FORM1: ECG
PREV MENU
WAVE FORM2: SPO2
WAVE FORM3: RESP


MAIN MENU
PREV MENU
WAVE FORM3:
> ECG
SPO2
RESP
OFF
WAVE FORM1: ECG

10.2 Paper Change

1

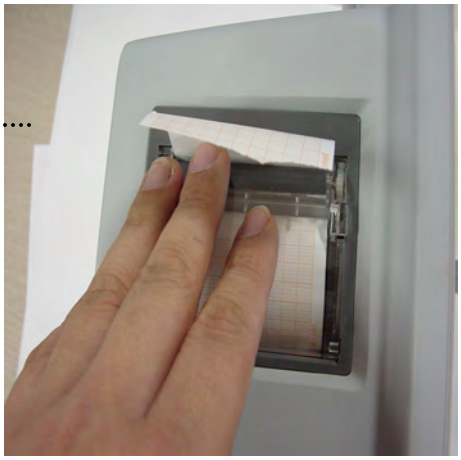
Open the window of the printer.

2

Insert the paper roll offered with the product into the printing unit. Place the roll in a proper way so that the printed paper can roll out upwards.

3

Press the printer window until it is properly shut. Inaccurate shutting may cause failure in printing.



11. MESSAGE LIST

Function	Message	Details
ECG	LEAD FAULT	Cable is not properly connected.
SpO_2	CHEK PROBE LEAD FAULT	Patient's finger is off the probe. Cable is not properly connected.
RESP	LEAD FAULT APNEA	Cable is not properly connected. APNEA gives an alarm.
NIBP	INFLATION FAILURE CHECK CUFF OVER PRESSURE DEFLATION FAILURE OVER TIME CUFF PRESSURE MEASUREMENT ERROR	Cuff hose is not properly connected. Cuff pressure is putting on excessively. Cuff is bent, preventing deflation. Measure time exceeds the preset Level. Measure signal absent
TEMP	LEAD FAULT	Cable is not properly connected.
ALARM	ALARM VOL.OFF SILENCED ALARM PAUSE 5MIN	Alarm volume is off. Alarm key is pressed once Alarm key is pressed twice
TREND	NO PATIENT DATA	No patient's data input.
PRINT	NO PAPER	No paper in the printer
SETUP	BATTERY LOW	Low battery

12. DEFAULT SETTING VALUE

1. Adult-ICU Mode

Alarm level

	High	Medium	Low	Message
Asystole	0			
Vfib/VTac	0			
V Tach	0			
HR		0		
NIBP		0		
SpO_2			0	
SpO_2-Rate				0
RR				0
RR-Apnea				0
T(˚C)				0

Parameter Limits

	Low	High
HR	50	150
NIBP-S	80	200
NIBP-M	40	140
NIBP-D	20	120
SpO_2	90	100
SpO_2-Rate	50	150
RR(RESP)	10	30
RR-Apnea	0	20
T(˚C/˚F)	30.0/42.0	86.0/107.6

Display

Patient Age	**Adult**
Color format	**Color**
Primary ECG	**II**
Arrhythemia	**Off**
Detect Pace	**Off**
Print Waveform2	**Off**
Print Waveform3	**Off**
Alarm Print	**On**
NIBP Auto	**Off**
NIBP Cuff Size	**Adult**
RR(RESP) Lead	**II**
Alarm Volume	**50%**
QRS Volume	**Off**
Pulse Volume	**Off**
ECG Lead Fault	**Low Alarm**
SpO_2 Probe Off	**Low Alarm**
Units for Height	**cm**
Units for Weight	**kg**
Temperature Units	**˚C**
NIBP Limit Type	**Systolic**
ECG Filter	**Monitoring**

2. Neonate-ICU Mode

Alarm level

	High	Medium	Low	Message
Asystole	0			
Vfib/VTac	0			
V Tach	0			
HR		0		
NIBP		0		
SpO_2			0	
SpO_2-Rate				0
RR				0
RR-Apnea				0
T(˚C)				0

Parameter Limits

	Low	High
HR	90	200
NIBP-S	40	100
NIBP-M	30	70
NIBP-D	20	60
SpO_2	88	100
SpO_2-Rate	90	200
RR(RESP)	15	100
RR-Apnea	0	15
T(˚C/˚F)	30.0/42.0	86.0/107.6

Display

Patient Age	**0~2 years**
Color format	**Color**
Primary ECG	**II**
Arrhythemia	**Off**
Detect Pace	**Off**
Print Waveform2	**Off**
Print Waveform3	**Off**
Alarm Print	**On**
NIBP Auto	**Off**
NIBP Cuff Size	**Neonate**
RR(RESP) Lead	**II**
Alarm Volume	**50%**
QRS Volume	**Off**
Pulse Volume	**Off**
ECG Lead Fault	**Low Alarm**
SpO_2 Probe Off	**Low Alarm**
Units for Height	**cm**
Units for Weight	**kg**
Temperature Units	**˚C**
NIBP Limit Type	**Systolic**
ECG Filter	**Monitoring**

3. Pediatric-ICU Mode

Alarm level

	High	Medium	Low	Message
Asystole	0			
Vfib/VTac	0			
V Tach	0			
HR		0		
NIBP		0		
SpO_2			0	
SpO_2-Rate				0
RR				0
RR-Apnea				0
T(˚C)				0

Parameter Limits

	Low	High
HR	70	180
NIBP-S	60	160
NIBP-M	40	120
NIBP-D	30	100
SpO_2	90	100
SpO_2-Rate	70	180
RR(RESP)	10	50
RR-Apnea	0	20
T(˚C/˚F)	30.0/42.0	86.0/107.6

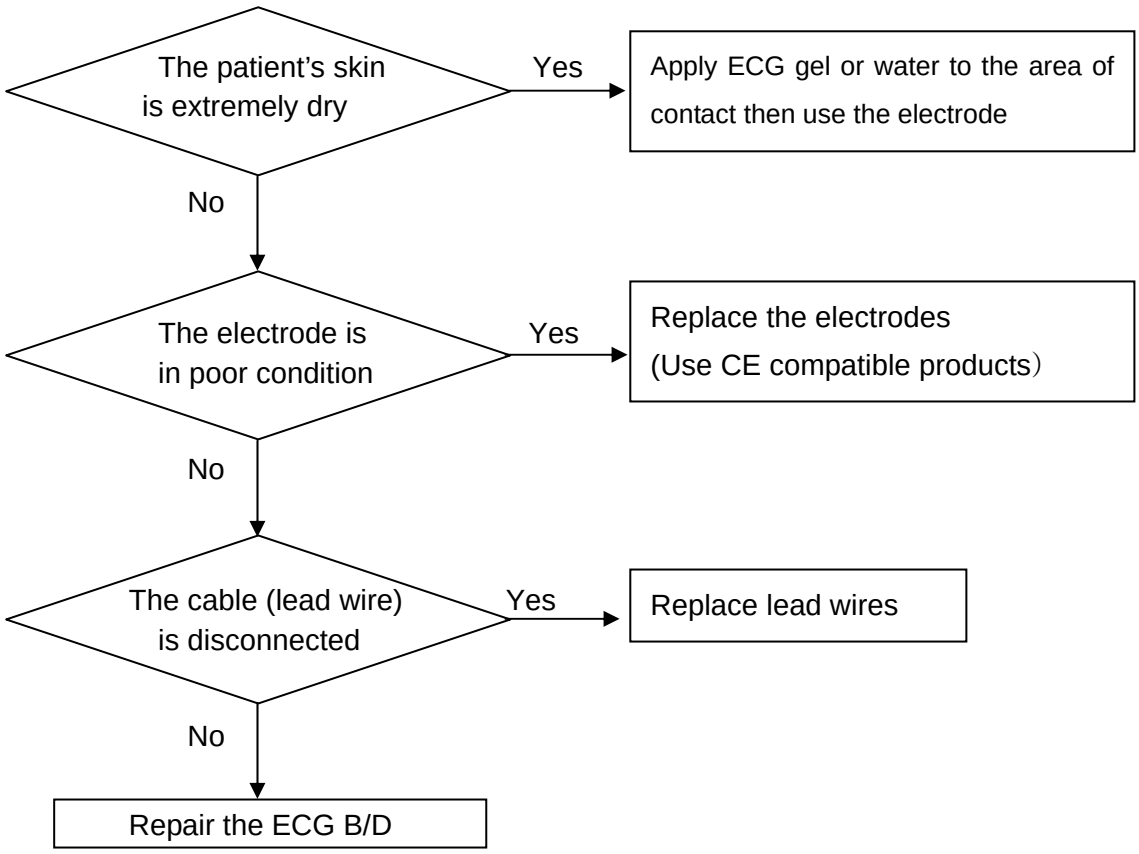
Display

Patient Age	**Adult**
Color format	**Color**
Primary ECG	**II**
Arrhythemia	**Off**
Detect Pace	**Off**
Print Waveform2	**Off**
Print Waveform3	**Off**
Alarm Print	**On**
NIBP Auto	**Off**
NIBP Cuff Size	**Adult**
RR(RESP) Lead	**II**
Alarm Volume	**50%**
QRS Volume	**Off**
Pulse Volume	**Off**
ECG Lead Fault	**Low Alarm**
SpO_2 Probe Off	**Low Alarm**
Units for Height	**cm**
Units for Weight	**kg**
Temperature Units	**˚C**
NIBP Limit Type	**Systolic**
ECG Filter	**Monitoring**

13. TROUBLE SHOOTING

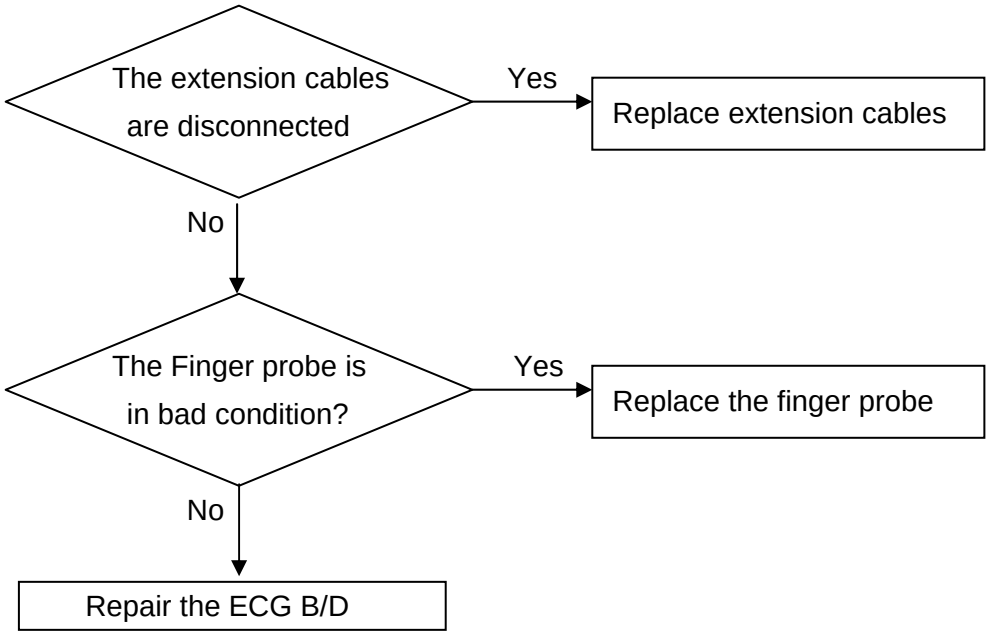
1. Noise in ECG

- Gel is dry
- Electrodes does not stick well to skin

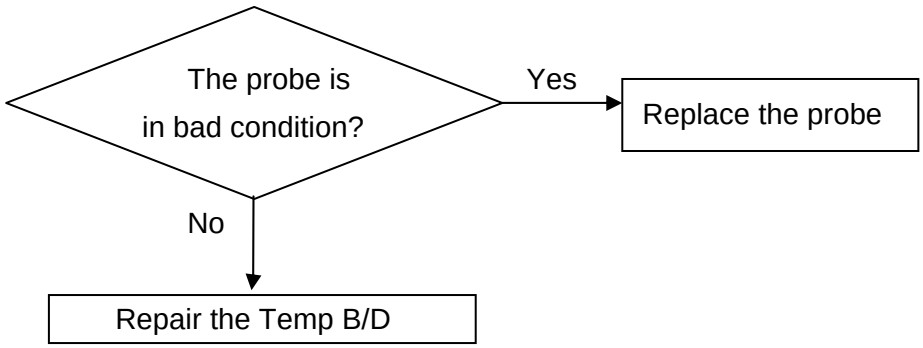


2. SpO_2 malfunction

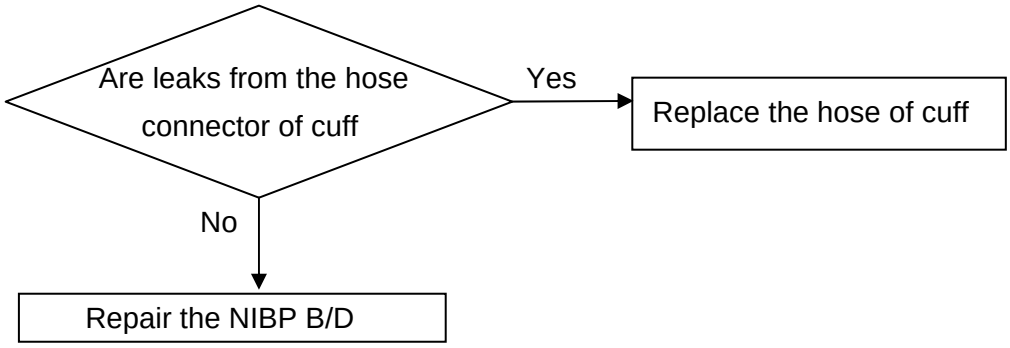
Connectors of the equipments are in bad condition?



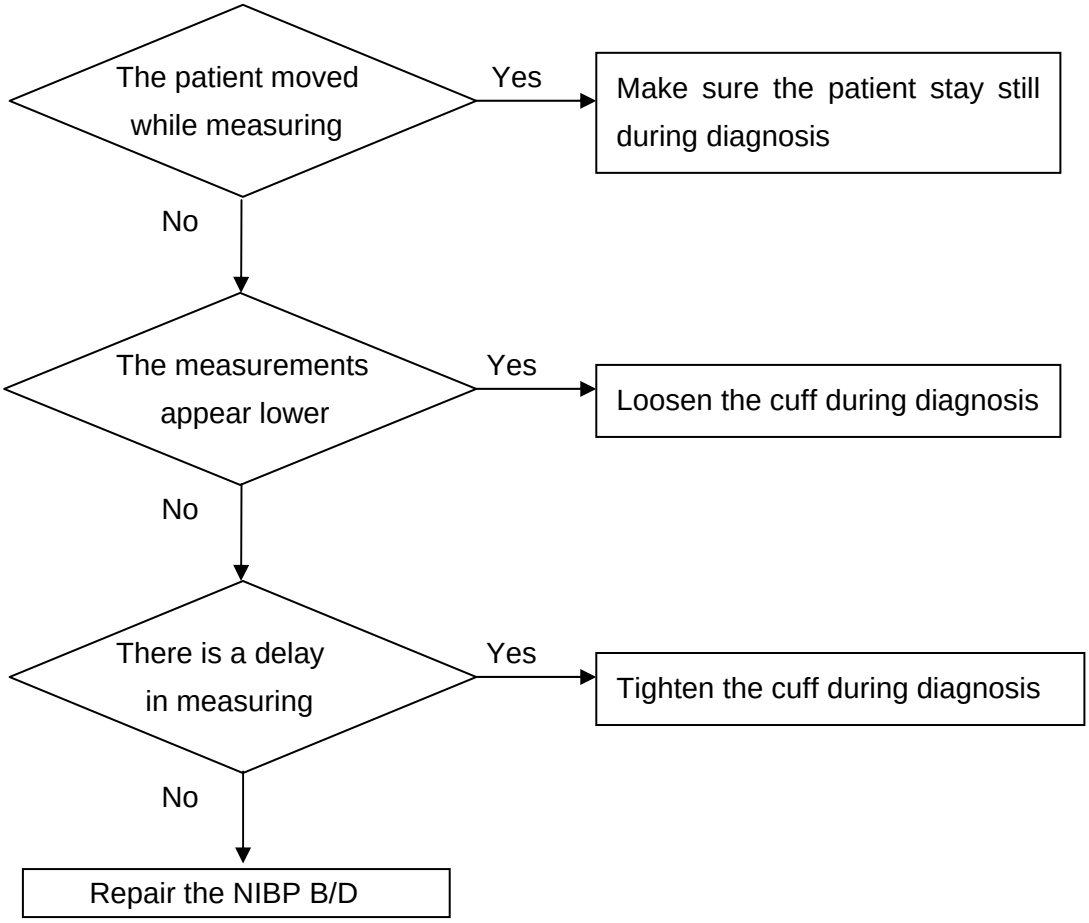
3. Temp malfunction



4. NIBP malfunction

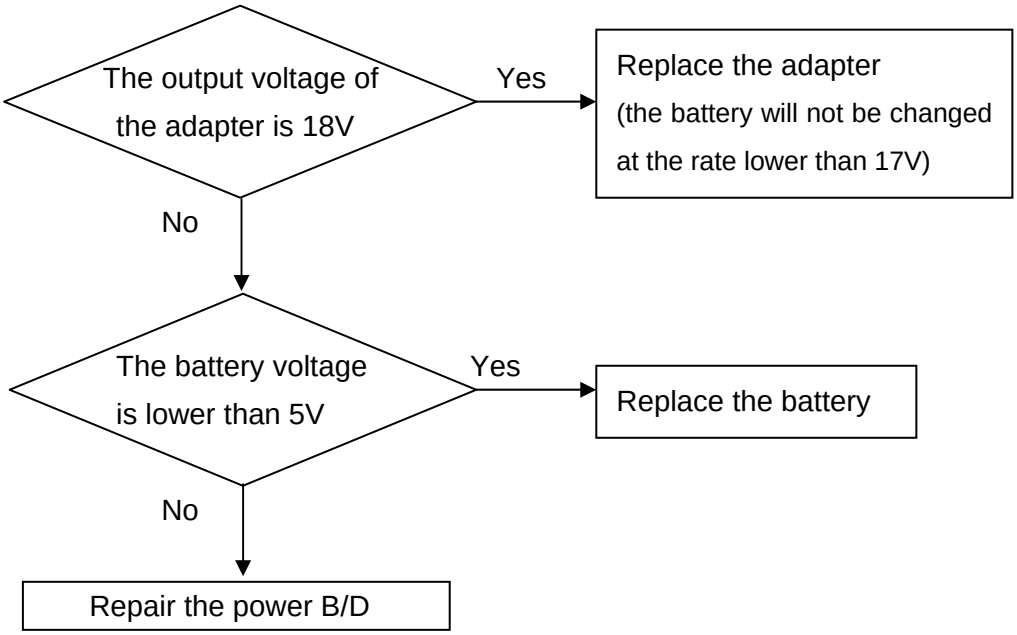


5. Abnormality in NIBP measurements

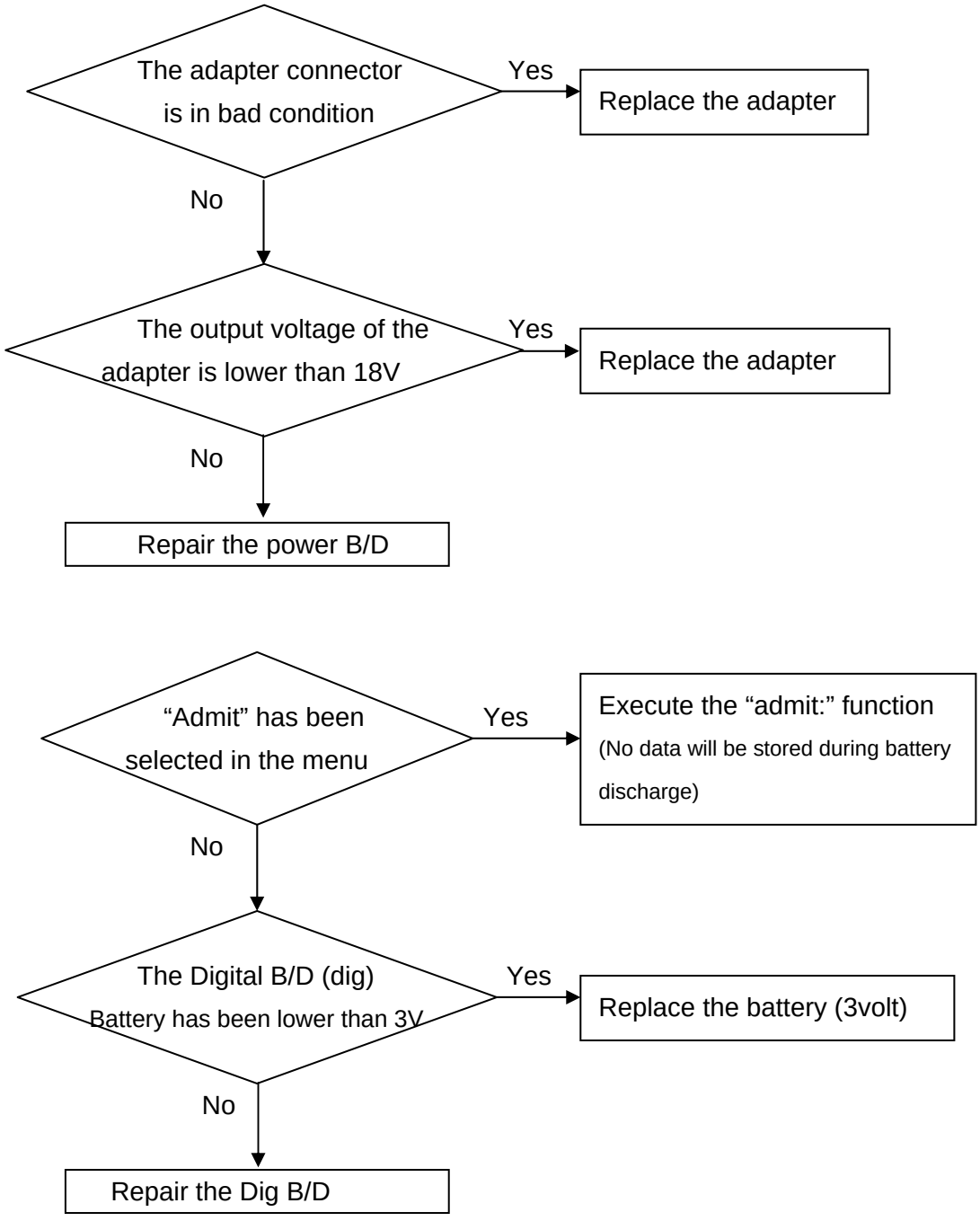


6. Failure in battery recharge

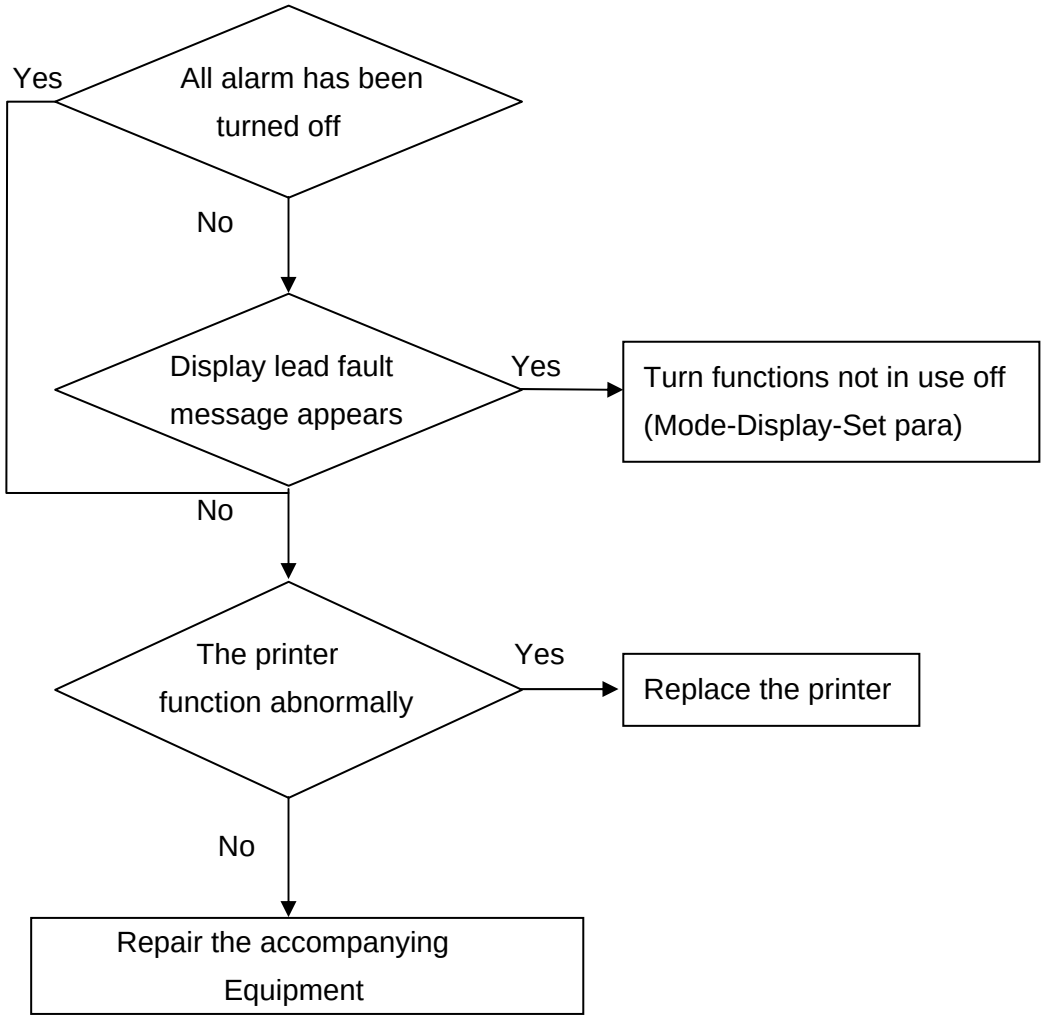
(the battery does not fully recharge in 6 hours or more)



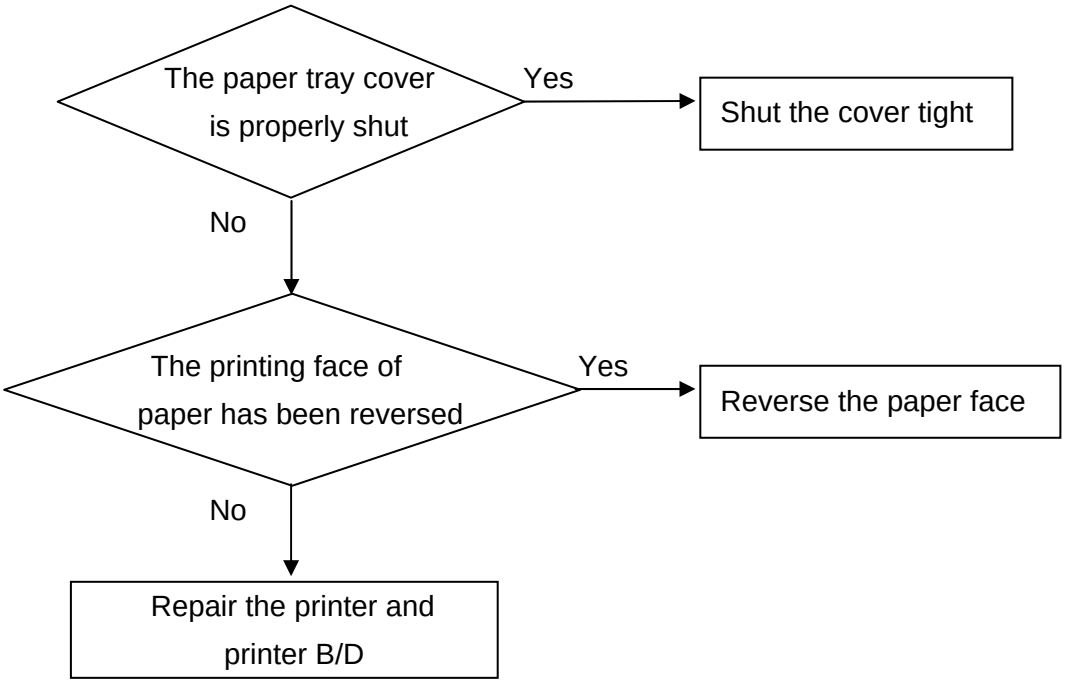
7. Power failure



8. Periodic noises



9. Print failure



14. SPECIFICATION

Ease of use

Customization

Special Features

Monitor Environmental Specifications

Power adaptor

Monitor Performance Specifications

Graphical and Tabular Trends

SpO2 Performance Specifications

Respirations Performance Specifications

NIBP Performance Specifications

ECG Performance Specifications

Temperature Unit Performance Specifications

Accessories included

OPTION

Ease of use

· Battery operation

· Attached printer

· Table and graphic trend

· Nellcor SpO_2 sensor interchanges

Additional Function

· Able to use auto mobile power supply

· LAN Connection

Monitor Environmental Specifications

· Operating Temperature： 15°C to 30°C (59°F to 86°F)

· Storage Temperature： - 10°C to 60°C (14°F to 140°F)

· Humidity： 20% to 95% RH

· Operating Attitude： 70(700) to 106Kpa(1060mbar)

Power

· AC 100-240V (50/60Hz)

· Adapter 18 V, 2.5 A

Monitor Performance Specifications

· Screen： 7" TFT LCD (800×480)

· Indicators

- Up to 3 wave patterns
- 3 levels of alarm sound
- Visual alarm
- Pulse sound
- handle flashing
- Battery status
- LED external power supply LED

· Interfaces

- Vehicles power supply：12 to 16 V DC, 3A max.
- Generating power for LAN, Wireless LAN : 5.0V max 0.9A

· Battery

- Li-ion battery
- Battery status display
- Operating time：2hours(with fully charged Battery)

· Thermal Printer(Optional)：internal printer

- Speed：25, 50 mm/sec
- Paper width：58 mm

Graphical and Tabular Trends

· Table Trend

- Memory Storage：128 hours
- Data Interval：1 minute
- Display Interval：1MIN, 5, 15, 30, 1HR

· Graphical Trend

- Display Period：30MINS, 60, 90, 3HRS, 6, 12

ECG capacity

· Lead :	3,5
· pulse rate range：	30 to 300 bpm
· pulse accuracy：	±3 bpm
· Bandwidth：	0.5 Hz to 40 Hz
· Display Sweep Speed：	2 5mm / sec
· ECG size (Sensitivity)：	0.5, 1, 2, 4 mV/cm
· Lead-off Detection with display indicator	
· Pace maker Detection Mode	
· Differential Input Impedance：	> 5 MΩ
· XCommon Mode Rejection Ratio：	> 90 dB at 50 or 60 Hz
· DC Input Range：	±5 mV
· Defibrillator Discharge：	< 5s
· Defibrillation Artifact Recovery Time：	< 8s

SpO_2 capacity

· Saturation Range：	0% to 100% oxygen proportion
· Pulse Rate Range：	30 to 254 bpm
· SpO_2 accuracy：	70% to 100% ±2 digits, 0% to 69% unspecified

· pulse accuracy： ±2 bpm

· Sensor Red 660nm, 2mW (typical)

Infrared 905nm, 2-2.4mW (typical)

· Minimum Signal: 0.05% modulation (Low perfusion level performance and

Amplitude limitation validation using FLUKE Index 2 Oximetry Simulator)

Respiration Performance Specifications

· Range： 5 to 120 breaths/min

· Accuracy： ±3 breaths/min

· Display Sweep Speeds：25mm/sec

NIBP capacity

· Technique： Oscillometric

· Measurement mode:

- Manual： Single Measurement
- Auto： automatic Intervals of 1MIN, 2, 3, 4, 5, 10, 15, 20, 30, 1HR, 2, 4, 8

· Pressure Display： 0 to 300 mmHg

· Blood Pressure Measurement Range:

- systolic ： 60 to 250 mmHg
- Mean Arterial Pressure ：40 to 235 mmHg
- Diastolic： 30 to 220 mmHg

Temperature Unit Performance Specifications

· Range ： 15°C to 45°C (59°F to 113°F)

· Accuracy ： 25°C to 45°C ± 0.1°C, 15°C to 24°C±0.2°C

· Sensor : YSI 400 Series compatibility

Accessories Included:

· 3Lead patient cable(3CBL-400, 3WIRE-400) 1 EA

· Electrodes(ECG SENS - 400) 10 EA

· NIBP tubing, 3m long(NBPCBL-400) 1 EA

· adult cuff, 25-35 Cm (ACUFF-400) 1 EA

· SpO_2 extension cable 2m (SPCBL-400) 1 EA

· SpO_2 sensor (SPASENS – 400) 1 EA

· DC adapter, 18VDC, 2.5A (MW160 Made in AULT Co., Ltd.) 1 EA

Option

· Temperature sensor (skin) (TEMPSENS-400)

· Printer Paper (PAPER-400)

· 5 lead patient cable (5CBL-400, 5WIRE-400)

Abbreviations and Symbols

Abbreviations and symbols which you may encounter while reading this manual or using the monitor are listed below with their meanings.

Abbreviations

A

A	amps
AaDO2	alveolar arterial oxygen gradient
ABG	arterial blood gas
AC	alternating current
ACCV	accelerated ventricular
ACC VENT	accelerated ventricular
ADT	adult
ANT	anterior
AO2 (aO2)	arterial oxygen saturation
AR	argon
ARRYTH	arrhythmia
ART	arterial
ASYS	asystole
Auto, AUTO	automatic
AUX	Auxiliary
a–vO2	arterial venous oxygen content difference
AVF	left foot augmented lead
AVG	average
AVL	left arm augmented lead
AVR	right arm augmented lead

B

BE	base excess
BGMY	bigeminy
BP	blood pressure
BP 1	blood pressure connector 1
BP 2	blood pressure connector 2
BPM	beats per minute
BRAD	bradycardia

BSA	body surface area
BT	blood temperature

C

C	Celsius
CAL	calibration
CALC	calculation
CALCS	calculations
CaO2	arterial oxygen content
CARD	cardiac
CC	computation constant
cc, CC	cubic centimeter
CCU	critical care unit
CEd	effective dynamic compliance
CH	channel
CI	cardiac index
cm, CM	centimeter
CO	cardiac output, carbonmonoxide
CO2	carbon dioxide
COHb	carboxyhemoglobin
COMM	communication
CP	cardiopulmonary
CPLT	couplet
CPP	cerebral perfusion pressure
CS	central station
CvO2	mixed venous oxygen content difference
CVP	central venous pressure

D

D	diastolic
DC	direct current
DDW	Direct Digital Writer
DEFIB, Defib	defibrillator
DES	desflurane
DIA	diastolic
DISCH	discharge
dyn	dyne

E

E	expired
ea–vO2	estimated arterial venous oxygen content difference
eCaO2	estimated arterial oxygen content
ECG	electrocardiograph
eCvO2	estimated mixed venous oxygen content eg for example
EMC	electromagnetic compatibility
EMI	electromagnetic interference
ENF	enflurane
eO2CI	estimated oxygen consumption
eO2DI	estimated oxygen delivery
eO2R	estimated oxygen extraction ratio
eQs/Qt	estimated shunt fraction
Esopho	esophageal
ESU	electrosurgical cautery unit
et al	and others
EtCO2, ETCO2	end-tidal carbon dioxide
ETO	Ethylene Oxide
EX, Exp	expired

F

F	Fahrenheit
FEM	femoral
FiO2	fraction of inspired oxygen
FR	French (catheter size)

G

g	gram
GTT/CC, gtt/cc	drops per cubic centimeter

H

HAL	halothane
Hb	hemoglobin
HbO2	oxyhemoglobin
HCO3	bicarbonate
HE	helium
Hgb	hemoglobin
HR	heart rate, hour

HT	height
Hz	hertz

I

I	inspired
IABP	intra-aortic balloon pump
ICP	intracranial pressure
ICU	intensive care unit
ie	that is
IN	inspired
Inc	incorporated
INF	infusion, inferior
INIT	initialization
Inj, INJECT	injectate
Insp	inspired
IRRG	irregular
ISO	isoflurane
ISU	inlet select unit
IT	injectate temperature
IV	intravenous

K

kg, KG	kilogram
kPa	kilopascal

L

L	liter, left
LA	left arm, left atrial
LAT	lateral
LBS	pounds
LCD	liquid crystal display
LD	lead
LED	light emitting diode
LL	left leg
LVSWI	left ventricular stroke work index

M

M mean,	minute
m	meter

MAP	mean arterial pressure
MCG	micrograms
MetHb	methemoglobin
MG	milligrams
MIN,	min minute
mL	milliliter
MM, mm	millimeters
MM/S	millimeters per second
MMHG, mmHg	millimeters of mercury
MRI	magnetic resonance image
MTR	motor
MUNITS	milliunits
mV	millivolt
MV	minute volume

N

N2	nitrogen
N2O	nitrous oxide
NBP	noninvasive blood pressure
NC	non-capture
NEO, Neo	neonatal
NET	network
NS	non-sense

O

O2	oxygen
OR	operating room

P

PA	pulmonary artery
PaCO2	partial pressure of carbon dioxide in arterial
PAD	pulmonary artery diastolic
Pa/FiO2	oxygenation ratio
PAM	pulmonary artery mean pressure
PaO2	partial pressure of oxygen in arterial blood
PAO2	alveolar pressure
PAUS	pause
PAW	pulmonary artery wedge pressure

PBAR	barometric pressure
PCO2	partial pressure of arterial carbon dioxide
PEAKP	end inspiratory pressure
PED	pediatric
PEEP	positive end expiratory pressure
pH	hydrogen ion concentration
PIP	peak inspiratory pressure
PO2	partial pressure of arterial oxygen
PPLAT	plateau pressure
PT-RR	patient respiration rate
PULM	pulmonary
PVC	premature ventricular complex
PvO2	partial pressure of oxygen in mixed venous
PVR	pulmonary vascular resistance
PVRI	pulmonary vascular resistance index
PWR	power

Q

QA	quality assurance
QRS	interval of ventricular depolarization
Qs/Qt	shunt fraction
QTY	quantity

R

R	rate, right
RA	right arm, right atrial
RESP	respiration
RHb	reduced hemoglobin
RHY	rhythm
RL	right leg
RM	respiratory mechanic
RMT ALM	remote alarm
RMT VID	remote video
RR	respiration rate
RTFC	artifact
RVSWI	right ventricular stroke work index

S

S	systolic
SaO2	arterial oxygen saturation
sec	second
SOL	solution
SP	special
SPEC	spectrometer
SpO2	arterial oxygen saturation from pulse oximetry
SUM	summation
SV	stroke volume
SvO2	mixed venous oxygen saturation
SVR	systemic vascular resistance
SVRI	systemic vascular resistance index
SYNC, Sync	synchronization
SYS	systolic

T

T1	temperature site 1
T2	temperature site 2
TACH	tachycardia
Temp, TEMP	temperature
TGMY	trigeminy
TIR	technical information report
TMP	temperature
TV	tidal volume

U

UAC	umbilical artery catheter
UVC	umbilical venous catheter

V

V	precordial lead
V	volt
VAC	volts AC (alternating current)
VBRADY	ventricular bradycardia
VBRD	ventricular bradycardia

VENT	ventilator
V-Fib, VFIB	ventricular fibrillation
VID	video
VNT	ventilator
VT	ventricular tachycardia
VTAC	ventricular tachycardia
V-Tach, V-TACH	ventricular tachycardia
VOL	volume

W

WT	weight

X

X	multiplier when used with a number (2X), denotes invalid data when used in place of a value on the display 12SL 12-lead ECG analysis
&	and
°	degree(s)
>	greater than
<	less than
–	minus
#	number
%	percent
±	plus or minus

PRODUCT WARRANTY

Product Name	**Patient Monitor**
Model Name	**B3**
Approval Number	
Approval Date	
Serial Number	
Warranty Period	**2 year from date of purchase**
Date of Purchase	
Customer Section	**Hospital Name :** **Address :** **Name :** **Phone :**
Sales Agency	
Manufacturer	

* Thank you for purchasing B3.

* The product is manufactured and passed through strict quality control and through inspection.

* Compensation standard concerning repair, replacement, refund of the product complies with "Consumer's Protection Law" noticed by Economic Planning Dept.

Manufactured by -

Bionet Co., Ltd :

#11F, E&C DREAM TOWER III, 197-33, GURO-DONG,

GURO-GU, SEOUL, SOUTH KOREA

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Distributor by -

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VIA MARCONI, 1 – 20060 GESSATE (MI) ITALY

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E-mail : export@gimaitaly.com

EC Representative -

MGB Endoskopische Gerate GmbH Berlin

Schwarzschildstr. 6, 12489 Berlin, Germany

TEL : +49(30)63927010 / FAX : +49(30)63927011

After Sales Service Center -

GIMA SPA

VIA MARCONI, 1 – 20060 GESSATE (MI) ITALY

Tel : ++39 02 953854209 Fax : ++39 02 95380056

E-mail : export@gimaitaly.com

Model Name : B3

GIMA warranty conditions

Congratulations for purchasing a GIMA product.
This product meets high qualitative standards both as regards the material and the production.
The warranty is valid for 12 months from the date of supply of GIMA.
During the period of validity of the warranty, GIMA will repair and/or replace free of charge all the defected parts due to production reasons. Labor costs and personnel traveling expenses and packaging not included.
All components subject to wear are not included in the warranty.
The repair or replacement performed during the warranty period shall not extend the warranty.
The warranty is void in the following cases: repairs performed by unauthorized personnel or with non-original spare parts, defects caused by negligence or incorrect use.
GIMA cannot be held responsible for malfunctioning on electronic devices or software due to outside agents such as: voltage changes, electro-magnetic fields, radio interferences, etc.
The warranty is void if the above regulations are not observed and if the serial code (if available) has been removed, cancelled or changed.
The defected products must be returned only to the dealer the product was purchased from. Products sent to GIMA will be rejected.

Disposal

Disposal: The product must not be disposed of along with other domestic waste.
The users must dispose of this equipment by bringing it to a specific recycling point for electric and electronic equipment.
For further information on recycling points contact the local authorities, the local recycling center or the shop where the product was purchased. If the equipment is not disposed of correctly, fines or penalties may be applied in accordance with the national legislation and regulations.

CE 0123

BIONET Co., Ltd. #1101, E&C Dream Tower III, 197-33, Guro-Dong, Guro-Gu, 152-848 Seoul - Korea

EC REP MGB Endoskopische Geräte GmbH Berlin, Schwarzschildstr. 6, 12489 Berlin - GERMANY